UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

DP Barcode: D276945
PCCode:056801
Date: August 17, 2002

MEMORANDUM:

SUBJECT: Response to Registrant's 30-day Error Correction Comments on the EFED Risk Assessment Chapter in Support of the Reregistration Eligibility Decision (RED) on Carbaryl

To: Anthony Britten, PM Team Reviewer
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Special Review and Reregistration Division (7508C)

FROM: E. Laurence Libelo, Ph.D., Environmental Engineer
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THRU: Betsy Behl, Chief
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The Environmental Fate and Effects Division (EFED) has reviewed the registrant 30-day (Phase I) error response from Aventis CropScience entitled "*Review of the Draft Environmental Fate and Ecological Risk Assessment of the Reregistration of Carbaryl*." EFED has revised its risk assessment for the reregistration eligibility decision (RED) and is attaching the revised document. Revisions to the chapter (identified below) reflect only those instances where an actual error was identified. Comments from the registrant that did not identify an actual error but rather were editorial in nature will be addressed after the public comment period (Phase II) has ended. However, several generic issues were raised by the registrant that EFED would like to comment on. These include endocrine disruption, the use of open literature to supplement core data submissions, status of Aventis' water-monitoring studies, and the role of new data submissions in characterizing risk in the current version of the RED.

Endocrine Disruption

The risk assessment chapter is not intended to resolve the endocrine disrupting potential of carbaryl. Rather, the chapter summarizes available ecological effect data; EFED believes there are sufficient data to raise concern regarding the endocrine disrupting potential of carbaryl. EFED is required to identify effects that it believes are consistent with responses to endocrine-mediated pathways. Those chemicals identified as potential endocrine disruptors such as carbaryl, will likely be subject to more refined testing for such effects once the appropriate testing procedures have been

identified. However, at this stage of the process EFED is simply identifying potential endocrine disruptors.

Open Literature

Open literature studies are not intended to fulfill guideline data requirements but rather they are intended to help reduce uncertainty and support concerns regarding risk. Additionally, EFED relies on open literature from peer-reviewed journals that require proposed publications to undergo the scrutiny of review prior to release to the general public. The registrant contends that toxicity data obtained from published literature are ". . . at times at least questionable and other times does not fulfill the requirements set by EPA for studies submitted by the registrant. Data of such poor quality should not be used as key information in the risk assessment." EFED has routinely relied on published literature particularly in cases where there are insufficient core data and/or the existing data introduce considerable uncertainty into the risk assessment process. In general, published literature is drawn from peer reviewed journals; while EFED does not have access to the original data on which these studies are based, it is assumed that the study conclusions have undergone some degree of scientific scrutiny to warrant publication.

Status of Aventis' Drinking Water Monitoring Studies

The registrant makes repeated reference to the drinking water monitoring study data that were submitted. The study is very limited in scope and it is unclear how sites that were monitored relate to locations where carbaryl has been used nationally. It is extremely unlikely that this study sampled peak concentrations. In addition, the study design did not allow EFED to evaluate the effect of drinking water treatment on carbaryl concentrations. The study is also of only limited usefulness for determining concentrations in surface water for use in ecological exposure assessment. Water bodies represented in the study are generally larger then those of concern for ecological exposure. The limitations on this study have been discussed in the reviews of the study interim reports.

Additional Data

In several instances, the registrant references recently submitted data as addressing uncertainties characterized in the RED. Since these data were not available when the draft RED was written, they were not captured in the RED. Depending on the quality of the new data, they may be included in the RED after they have been reviewed. However, the 30-day error response phase is not intended to represent an opportunity to submit additional data. Additionally, if data are provided that demonstrate that certain environmental fate and ecological effects endpoints might be substantially different than those used in the RED, it does not discount the reliability and/or utility of the original studies. For example, if the newly submitted 2-generation rat study provides a no-observe effect concentration which is significantly less sensitive than the endpoint used from the rat developmental study, then it is likely that EFED would continue to use the results of the original developmental study, *i.e.*, the most sensitive endpoint, to evaluate chronic toxicity.

In the attached document (**Attachment A**) each of the registrant's comments is addressed. The attachment is in three sections, *i.e.*, General Comments, Transmittal and RED Document Line-by-Line Review of the Carbaryl RED Chapter, and Discussion. In the line-by-line review, the registrant cites specific EPA comments and then provides their response to the comment. In all three sections, the EFED response to discussions and/or comments is entitled "*EFED Response*". In many cases the registrant has provided constructive comments on the EFED science chapter and has helped to assure the document's accuracy. Overall though, the registrant's comments have not affected the basic

concerns and uncertainties identified in environmental fate and ecological effects assessment of carbaryl.

Attachment A. EFED Responses to 30-day Error Correction Comments by Registrant

CARBARYL

PC Code No. 056801; Case 0080

Review of the Draft Environmental Fate and Ecological Risk Assessment for the Reregistration of Carbaryl

August 6, 2001

Aventis CropScience
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Research Triangle Park, NC 27709

General Comments

The EFED draft chapter of the carbaryl RED is very thorough using a wealth of references. The use of published literature over submitted data is significant. The quality of the published literature is at times at least questionable and other times does not fulfill the requirements set by EPA for studies submitted by the registrant (e.g. thorough description of test conditions, clear identification of the test material, analytical verification, GLP etc.). Data of such poor quality should not be used as key information in the risk assessment. For the 30-day response not all literature references could be verified or the quality ascertained.

***EFED Response**:*

EFED feels that all available relevant information should be used in evaluating risk of pesticides with long registration histories. As in other risk assessments literature data were used to supplement and to help evaluate registrant submitted data. Literature data were also used when required core data were not submitted. Literature data were evaluated by EFED scientists prior to the data's inclusion into the risk assessment and data of questionable validity were not used.

There is a high level of redundancy in the document making it difficult to read. Reducing repetitions to a minimum would facilitate the reading.

***EFED Response**:*

While EFED agrees that the chapter includes some redundancy, this does not represent a factual error in the document. EFED has found utility in repeatedly emphasizing certain themes to underscore concern or uncertainty.

We believe it is inappropriate to include DERs [data evaluation records] in the RED Chapters. A summary of study findings is already presented in the document. DERs should be made available to the public through the regular procedure under the Freedom of Information Act after they have been reviewed and cleared for confidential business information.

***EFED Response**:*

EFED concurs with the registrant's comments that DERs should be made available to the public under the Freedom of Information Act after they have been reviewed and cleared for confidential business information.

The use of carbaryl on barley, oats, rye, cotton, and livestock are cancelled . It should be noted that Aventis CropScience labels for the technical materials and the end-use products containing carbaryl were amended to delete these uses. The Agency has already approved the labeling changes (please refer to HED response document, Section III for details).

***EFED Response**:*

The cancelled uses have been removed. The document reflects uses that were supported at the time the chapter was written; EFED does not have the resources to revise chapters to remain consistent with current mitigation measures; however the chapter does provide a better understanding of why certain mitigation agreements were reached.

Aventis CropScience will no longer support the use of carbaryl on poultry (direct application and poultry quarters treatment). We will shortly submit a request for cancellation of these uses in accordance with section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (please refer to HED response document, Section III for details).

Aventis CropScience is in the process of conducting, or has scheduled, studies relevant to the refinement of the environmental risk assessments for carbaryl and the major degradate 1-naphthol. These studies are as follows:

- Rate and Route of Aerobic Degradation in Soils. These studies have been initiated with parent carbaryl applied to four diverse U.S. soils. The data are intended to provide additional half-life determinations for parent carbaryl and the major degradate 1-naphthol.
  Expected completion date: March 2002
- Aerobic Aquatic Metabolism in Two Water/Sediment Systems. These studies have been initiated with parent carbaryl applied to two distinct U.S. water/sediment systems. The data are intended to provide additional half-life determinations for parent carbaryl and the major degradate 1-naphthol. In addition, further identification of additional degradation products is anticipated.
  Expected completion date: March 2002
- Adsorption and Desorption of 1-Napthol to five soils. This study has been scheduled to evaluate the adsorption and desorption of the major carbaryl degradate to five soils/sediment. The data are intended to provide information necessary to evaluate the environmental risks from 1-naphthol in standard models.
  Expected completion date: March 2002

***EFED Response**:*

These studies will be reviewed and evaluated when they are received and if the studies are determined to be scientifically valid, they will be used in future assessments.

For the reregistration process in the EU, Aventis CropScience is in the process of conducting, or has scheduled, studies relevant to the refinement of the ecotoxicological risk assessments for carbaryl and the major degradate 1-naphthol. These studies are as follows:

Studies with Carbaryl:

Acute oral LD50 in mallard ducks
Dynamic acute LC50 in bluegill sunfish
Acute toxicity in *Daphnia*

Acute toxicity in *Chironomus riparius*
Toxicity in *Selenastrum capricornutum*
Acute oral and contact toxicity in honeybees
14-d toxicity in earthworms
Effects on soil microorganisms (nitrification/carbon cycle)
Effect on sewage treatment

Studies with 1-naphthol

Early life-stage study in fathead minnow
Acute toxicity in *Daphnia*
Acute toxicity in *Daphnia* in presence of sediment
Chronic toxicity in *Daphnia*
14-d toxicity in earthworms

Formulated Product

Vegetative Vigor
Toxicity in *Selenastrum capricornutum*
Acute oral and contact toxicity in honeybees
Effect on non-target arthropods
14-d toxicity in earthworms
Effects on soil microorganisms (nitrification/carbon cycle)

Ecotoxicological Risk Assessments

Aventis has pointed out several errors in the PRZM input parameters (see comments made to Tables 5 and 6 of the draft RED), overly conservative estimates of foliar dissipation half-lives and changes in ecotoxicology study endpoints. This indicates that a re-calculation of the EECs and risk quotients are warranted in a number of instances.

***EFED Response**:*

EFED has reviewed the estimated environmental concentrations [EECs] and does not agree with Aventis' perspective on PRZM input parameters. Specific comments are addressed in the appropriate sections below.

Endocrine Disruption

Reports in the open literature on the reproductive effects of carbaryl in wild mammals are at best ambivalent. The recently submitted 2-generation study in rats demonstrates the absence of reproductive effects. As EPA pointed out, findings reported in the literature were made at concentrations well above the highest peak concentration modeled. Therefore these findings are irrelevant for a risk assessment and at the current stage of discussion about endocrine disruption. If the concern about the endocrine potential of carbaryl persists, the issue should be revisited once the Agency's endocrine disrupter screening and testing program as well as a policy on how to

incorporate positive findings into an ecological risk assessment have been fully developed.

***EFED Response**:*

The ecological risk assessment does not conclude that carbaryl is an endocrine disrupter. EFED has cited open literature and has noted effects in chronic reproduction studies that are consistent with endocrine-mediated effects. EFED is uncertain regarding the endocrine disrupting capacity of carbaryl and is therefore requesting additional data when the appropriate testing procedures have been identified.

Mobility

The classification of carbaryl as mobile to very mobile is inconsistent with measured K_{oc} values of 177 to 249 (MRID 43259301). According to the widely used classification scheme of McCall, *et al.* (1980) wherein K_{oc} values between 150 and 500 denote medium mobility in soil, carbaryl would be classified as having medium mobility in most soils. This classification of medium mobility is further supported by the acceptable column leaching study (MRID 43320701) in which aged carbaryl residues were only slightly mobile in a number of soils. The mobility of carbaryl would be expected to be higher in sandy soils or in soils of low organic matter.

***EFED Response**:*

There are a number of classification schemes available and EFED does not agree that Macall et al 1980 is the definitive one. However, EFED has revised the chapter to read that "Carbaryl is considered to be moderately mobile in soils."

1-Napthol Fate and Transport

The Agency is requiring additional information on the persistence and mobility of 1-naphthol, a major environmental degradate of carbaryl. However, a half-life for 1-naphthol of less than 1 day can be calculated from the carbaryl aerobic soil metabolism study (MRID 42785101). The data from this study demonstrate that under aerobic soil conditions the formation and decline of 1-naphthol, starting from parent carbaryl, is complete in less than 14 days. This half-life can be used for preliminary environmental fate modeling to estimate EECs for 1-naphthol.

***EFED Response**:*

Based on the aerobic soil metabolism study of carbaryl it does appear that 1-naphthol degrades rapidly. However, there are a number of processes occurring simultaneously in the test system. It is not possible to solve for the multiple degradation and sorption/desorption rate constants from the limited data provided. The registrant is encouraged to provide additional data to resolve this uncertainty.

The EPA suggested that 1-naphthol is not strongly sorbed to soil. Additional information available in the literature demonstrates that the sorption of 1-naphthol to soil is stronger than that seen for

carbaryl itself. Hassett *et al.* (1981) has demonstrated that the sorption of 1-naphthol was the result of sorption to organic carbon resulting in K_{oc} values between 431 and 15,618. These data indicate that 1-naphthol is less mobile and less susceptible to leaching than carbaryl itself, and they demonstrate that at least a portion of the 1-naphthol residue is tightly sorbed to soil constituents. (A copy of this article is being submitted with the response to the draft RED.) To meet the requirement for information on the adsorption and desorption of 1-naphthol by the Agency, the registrant is conducting an adsorption/desorption study to meet the 163-1 guideline. Study results should be available for submission to the Agency in the first quarter of the calendar year 2002.

EFED Response:

EFED will review the data on the mobility of 1-naphthol when it is submitted. EFED agrees that literature data indicated that the degradate is less mobile then the parent.

Surface Water/Drinking Water

Aventis disagrees with EPA that the modeling simulations provide a conservative, though not unreasonable, estimate on possible concentrations in drinking water. Drinking water concentrations derived from PRZM/EXAMS greatly overestimate the potential exposure to carbaryl in drinking water, generally by several orders of magnitude. Results from the drinking water monitoring program conducted by the registrant provides a 'real world' assessment of the potential for human exposure to carbaryl in drinking water derived from surface water.

EFED Response:

EFED has reviewed the registrant's drinking water survey, and has discussed its limitations in the RED chapter and elsewhere. The study is very limited in scope and it is unclear how sites that were monitored relate to locations where carbaryl has been used nationally. It is extremely unlikely that this study sampled peak concentrations. Until a detailed description of how the sampling locations were chosen and how those sites relate to the rest of the country has been evaluated, it is not possible to use this small-scale study in our assessment. This information was submitted as part of the registrant's 30-day comment period response. It will be reviewed along with other submitted data and included in future risk assessments.

Ground Water

EPA summarized information on the detection of carbaryl in groundwater from the EPA Pesticides in Groundwater Database, the EPA STORET database and the NAWQA database. Each of the databases shows a pattern of very low levels of carbaryl detection in few groundwater resources. These analyses confirm several statements made by the Agency that carbaryl has limited potential to impact groundwater resources. However, on page 2 of the Memorandum issued June 28, 2001, in conjunction with the EFED RED chapter for carbaryl, EPA is requiring additional information on "surface and groundwater monitoring in urban and suburban use areas (non-guideline)." Based on the characteristics of carbaryl and the available data demonstrating limited impact of carbaryl on ground water resources, additional studies to evaluate the potential for carbaryl to contaminate

groundwater are unnecessary and unwarranted.

***EFED Response**:*

Carbaryl use in agricultural setting is expected to have only limited impact on groundwater resources. However, because of its widespread use by homeowners, it is likely that groundwater impacts will be greatest in residential settings. EFED does not require additional data for groundwater contamination evaluation (e.g. prospective groundwater studies) for agricultural uses but does for residential use.

Line-by-Line Review of the Carbaryl EFED RED Chapter

Transmittal Document

Data Gaps

Environmental Fate and Transport

Page: 2 Paragraph: 1 Line: 1

EPA comment:

Fate information on the degradation product 1-naphthol is required.

1. Mobility – adsorption and desorption studies for the 1-naphthol degradate (163-1)
2. Persistence – aerobic soil metabolism study on 1-naphthol

Aventis' response:

Literature data (Hassett *et al*. 1981) on the adsorption of 1-naphthol are provided in this response. Aventis is in the process of conducting an additional adsorption/desorption study on 1-naphthol and intends to submit study data to EPA by March 2002.

The degradation of 1-naphthol under aerobic soil conditions has been widely reported in the literature. Several citations are included in the EPA draft RED. The half-life of 1-naphthol estimated from the acceptable aerobic soil persistence study on carbaryl (MRID 42785101) is less than 1 day. Aventis is conducting additional laboratory aerobic soil degradation studies on carbaryl that will be used to provide additional determinations of the half-life for the degradate 1-naphthol and satisfy the Agency's requirement for data on the persistence of 1-naphthol. Aventis intends to submit these study data to EPA by March 2002.

***EFED Response**:*

EPA will review and evaluate the new data when it is submitted and will incorporated it into future risk assessments.

From the aerobic soil study it does appear that 1-naphthol degrades rapidly. However, there are a number of processes occurring simultaneously in the test system, and it is not possible to solve for the multiple degradation and sorption/desorption rate constants from the limited data provided.

Water Resources

Page: 2 Paragraph: 3 and 4

EPA comment:

"*EFED believes that adequate data are available to support the conclusions reached for carbaryl's impact on surface water and groundwater quality with the exceptions noted below. Additional information is needed to characterize the impact of the degradate 1-naphthol [in] groundwater and surface water. ...Surface and groundwater monitoring in urban and suburban use areas (non-guideline)"* are required.

Aventis' response:

The surface water-monitoring program conducted by Aventis includes monitoring in urban and suburban use areas. Aventis believes that the need for information on the degradate 1-naphthol will be satisfied by the aerobic soil and adsorption/desorption data that will be submitted to the Agency. These data can be used to evaluate the availability of 1-naphthol using established EPA modeling guidelines. The Agency's proposed requirement for groundwater monitoring is unnecessary and is addressed in Aventis' response to Agency comments in the draft RED.

***EFED Response**:*

EFED will review all additional data when they are submitted. New data will be included in future risk assessments.

EFED has reviewed this small-scale study and does not agree with the registrant's assessment. The limitations of the study have been described in the RED chapter.

Ecological Effects Data requirement

Page: 2

EPA comment:

The ecological toxicity database is complete except for:

6. Aquatic Plant Growth Guideline 122-2

Aventis' response:

The data requirement should be deleted. Aquatic plant growth studies were submitted to the Agency in 1992. An October 04, 2000 OPP Guideline Status Report (Chemical Review Management System) lists the guideline 122-2 status as "Acceptable/Satisfied". The studies are:

MRID No.	Title	Acceptability Code
42372101	Lintott, D. (1992) Carbaryl Technical: Acute Toxicity To The Freshwater Blue- Green Alga, *Anabaena flos-aquae*, Under Static Test Conditions: Lab Project Number: J9112004E. Unpublished Study Prepared By Toxikon Environmental Sciences. 53 P. *June 25, 1992*	Upgradable
42372102	Lintott, D. (1992) Carbaryl Technical: Acute Toxicity To Duckweed, *Lemna gibba* G3, Under Static Test Conditions: Lab Project Number: J9112004G. Unpublished Study Prepared By Toxikon Environmental Sciences. 53 P. *January 1, 1992*	Upgradable
42372802	Lintott, D. (1992) Carbaryl Technical: Acute Toxicity To The Freshwater Green Alga, *Selenastrum capricornutum* Under Static Conditions: Lab Project Number: J9112004C. Unpublished Study Prepared By Toxikon Environmental Sciences. 53 P. *June 9, 1992*	Acceptable

MRID No.	Title	Acceptability Code
42431601	Lintott, D. (1992) Carbaryl Technical: Acute Toxicity To The Freshwater Diatom, *Navicula pelliculosa*, Under Static Test Conditions: Lab Project Number: J9112004F. Unpublished Study Prepared By Toxikon Environmental Sciences. 52 P. *August 10, 1992*	Acceptable
42431602	Lintott, D. (1992) Carbaryl Technical: Acute Toxicity To The Saltwater Diatom, *Skeletonema costatum*, Under Static Test Conditions: Lab Project Number: J9112004D. Unpublished Study Prepared By Toxikon Environmental Sciences. 49 P. *August 10, 1992*	Supplemental

***EFED Response**:*

EPA requires data on 5 aquatic plant species. Only two of the five species provided data that were classified as acceptable and as having fulfilled guideline test requirements. Therefore, EFED is requesting that aquatic plant studies are repeated following EPA guidelines.

Page: 2

EPA comment:

The ecological toxicity database is complete except for:

7. Submission of a FETOX amphibian toxicity study is required.

Aventis' response:

The data requirement should be deleted. From the published results it is evident that carbaryl is practically non-toxic to the bullfrog. Effects in plain leopard frogs are reported at levels well above environmental concentrations. These results were obtained testing U.S. native species. In the proposed FETOX assay, a non-native species *Xenopus laevis* is used. This African species is unique in its behavior. Neither the species nor the test methods are suitable for ecotoxicological purposes. As the risk to amphibians can be evaluated from the studies cited, and as the effects are only at levels well above the EEC, this study should not be required.

***EFED Response**:*

While EFED is concerned about the documented effects of carbaryl on native frogs, it will not require the FETOX study at this time. However, when appropriate test methods have been developed for demonstrating endocrine disrupting effects, EFED will request that carbaryl undergo these tests to better understand the developmental toxicity of carbaryl.

Label Information

Page: 3

EPA comment:

For terrestrial and residential uses:

1. "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

Aventis' response:

Similar language is already present on Aventis' SEVIN® labels.

***EFED Response**:*

The label language that EFED is requesting is standard language that is consistent with the risks identified for this chemical.

Page: 3

EPA comment:

For terrestrial and residential uses:

3. "This product may contaminate water through drift of spray in wind. This product has a high potential for runoff for several days after application after application (sic). Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product.

   Household labels – Avoid applying this product to ditches, swales, and drainage ways. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours.

   Agricultural Label – A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."

Aventis' response:

Aventis would like to further discuss appropriate label language with the Agency. However, it should be noted that light to moderate rainfall (or irrigation) after application will also help move carbaryl residues deeper into the soil, thus making them less susceptible to runoff. The language in the last sentence should be changed to read, "…when *heavy* rainfall is….".

***EFED Response**:*

EFED believes that it is difficult to predict rate at which rain will fall and that the degree of runoff from or penetration into soil relative to the amount of rainfall depends on the consistency of the soil. The recommended label language is standard. This is not an error. Further discussion on this topic is more appropriate in a later phase of the reregistration process.

Page: 3

EPA comment:

For terrestrial and residential uses:

4. This pesticide is toxic to fish and aquatic invertebrates.

Aventis' response:

Aventis' SEVIN labels currently state "This product is extremely toxic to aquatic and estuarine invertebrates."

***EFED Response**:*

EFED has requested label language to mitigate risks to both freshwater and estuarine/marine fish and invertebrates.

Page: 3

EPA comment:

For terrestrial and residential uses:

5. This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

Aventis' response:

Aventis' SEVIN labels currently contain similar language.

***EFED Response**:*

The label language that EFED has requested is intended to emphasize the risk to bees when plants are blooming.

1.0 Summary and Environmental Risk Conclusions

Risk to Terrestrial Organisms

Page: 1 Paragraph: 4 Line: 2

EPA comment:

As discussed in pp. 44 - 45 and in Appendix D.

Aventis' response:

The mammalian risk quotients are discussed on pages 48 to 50 and in Appendix C, not as described in this text.

***EFED Response**:*

EFED concurs with the registrant's comments. The references to specific pages and to the appendix have been deleted.

Fate and Water Assessment

Page: 3 Paragraph: 5 Line: 3

EPA comment:

…in the U.S.G.S NAQWA program. NAQWA…

Aventis' response:

The abbreviation for the U.S.G.S. program is NA**WQ**A

***EFED Response**:*

EFED concurs with the registrant's comment and has corrected the references to NAWQA acronym throughout the document.

Page: 5 Paragraph: 1 Line: 7

EPA comment:

…estimate of possible concentrations drinking water.

Aventis' response:

missing word – …concentrations "in" drinking…

***EFED Response**:*

EFED concurs with the registrant's comment and has included the word "in".

Page: 5 Paragraph: 4 Line: 4

EPA comment:

…hydrolyzes in neutral (half-life = 12 days) and alkaline environments (pH 9 half-life = 3.2).

Aventis' response:

Missing units of after second half-life. The units are hours, so "= 3.2 hours)".

***EFED Response**:*

EFED concurs with the registrant's comment and has included the proper units, i.e., hours.

Page: 5 Paragraph: 4 Line: 5

EPA comment:

…photolysis in water with a half-life of 21 days

Aventis' response:

this is for photolysis in sterile water, not microbially-active water, so the phrase would be more precise as "…photolysis in sterile water…".

***EFED Response**:*

EFED concurs with the registrant's comment and has changed the wording to read "Carbaryl is degraded by abiotic photolysis . . .."

Page: 5 Paragraph: 4 Line: last

EPA comment:

(K_f =1.7 to 3.2).

Aventis' response:

The upper value K_f for carbaryl should be listed as 3.5 as referenced by EPA elsewhere (e.g. Table 3, page 20) in the document.

***EFED Response**:*

EFED concurs with the registrant's comment and has changed the range of K_f to read 1.7 – 3.5.

2.0 Introduction

Page: 6 Paragraph: 2 Line: 1-3

EPA comment:

Carbaryl (1-naphthyl N-methylcarbamate) is a broad-spectrum carbamate insecticide and acaricide registered for control of over 300 species of insects and mites on over 100 crop and noncrop use sites, including homeowner uses; pet, poultry, and livestock uses;…

Aventis' response:

Carbaryl is no longer registered for use on livestock. Aventis CropScience will not support the reregistration of the use on poultry (direct application and poultry quarters treatment). We will shortly submit a request for cancellation of this use in accordance with section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

EFED Response:

At this time, carbaryl is registered for use on livestock. When the cancellation is processed the wording will be changed for future risk assessments.

Page: 6 Paragraph: 3 Line: 2-3

EPA comment:

Approximately 2.5 million pounds of carbaryl are applied annually in the U.S. A map showing the widespread use of carbaryl in agriculture is shown in figure 1.

Aventis' response:

Summation of the data in Figure 1 gives a total of approximately 3.3 million pounds of carbaryl. Both the 2.5 and 3.3 million-pound figures are inconsistent with the value of 4 million pounds cited on page 35. The 2.5 million pounds is an average of usage over 1987 to 1996 developed in a memo by Frank Hernandez, July 21, 1998. The value of 2.5 million pounds in the text should be qualified with the additional information on the fact that it is an average for usage over 1987 to 1996 and is not a value for a single year.

EFED Response:

EFED concurs with the registrant's comments and the text has been revised.

Page: 7 Paragraph: 1 Line: 3-4

EPA comment:

Carbaryl is also used extensively for residential and other non-agricultural uses, being the second most commonly insecticide (sic) used in the home.

Aventis' response:

Carbaryl is not registered for use inside homes. It is registered for use outdoors in the lawn and garden around homes. In addition, an evaluation of the Vista (Triad) data for the last seasonal year from October 1999 to September 2000 shows retail sales for carbaryl at 18.7 million dollars. Carbaryl is listed as number 7 based on retail sales behind other active ingredients such as chlorpyrifos, diazinon, imidacloprid, hydramethylnon and tralomethrin. Therefore this sentence would be more appropriately worded as: "Carbaryl is also used for residential and other non-agricultural uses, being the seventh most commonly used insecticide around the home."

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "Carbaryl is also used for residential and other non-agricultural uses, being the seventh most commonly used insecticide around the home."

Page: 7 Figure 1

EPA comment:

Figure 2

Aventis' response:

This is labeled as Figure 2 when it is Figure 1

***EFED Response**:*

EFED concurs with the registrant's comments and the figure showing carbaryl use in agriculture has been relabeled as Figure 1.

3.0 Integrated Risk Characterization

Introduction

Page: 8 Paragraph: 1 Line: last

EPA comment:

Carbaryl is mobile to very mobile in the environment (K_f =1.7 to 3.2).

Aventis' response:

The upper value K_f for carbaryl should be listed as 3.**5** as referenced by EPA elsewhere (e.g. Table 3, page 20) in the document. The classification of carbaryl as mobile to very mobile is inconsistent with measured K_{oc} values of 177 to 249. According to the widely used classification scheme of McCall *et al.* carbaryl would be classified as having medium mobility in soil. This classification of medium mobility is further supported by the

acceptable column leaching study (MRID 43320701) in which carbaryl residues were only slightly mobile in a number of soils.

***EFED Response**:*

There are many classification systems available; EPA does not agree that the McCall et al. classification is the definitive classification. For example, ASTM (1996) puts K_{oc} of 177 in the medium mobility class approaching the high class. EFED has however revised the chapter to read that "Carbaryl is considered to be moderately mobile in soils."

Aquatic Organisms

Page: 10, Paragraph: 1, Line: 13

EPA comment:

Submission of a FETOX amphibian toxicity study is encouraged.

Aventis' response:

The data requirement should be deleted. From the published results it is evident that carbaryl is practically non-toxic to the bullfrog. Effects in plain leopard frogs are reported at levels well above environmental concentrations. These results were obtained testing U.S. native species. In the proposed FETOX assay a non-native species *Xenopus laevis* is used. This African species is unique in its behavior. Neither the species nor the test methods are suitable for ecotoxicological purposes. As the risk to amphibians can be evaluated from the studies cited, and as the effects are only at levels well above the EEC, this study should not be required.

***EFED Response**:*

EFED concurs that the FETOX assay may not represent the most appropriate test for examining the effects of carbaryl on amphibian behavior and development; therefore, EFED is not requiring the study at this time. EFED is however concerned about the effects of carbaryl on amphibians and particularly the developmental effects. When appropriate test methodologies have been identified for examining endocrine disrupting effects, EFED will request that carbaryl undergo these toxicity tests.

Page: 10, Paragraph: 3, Line: 6/7

EPA comment:

…resulting in a temporary impairment of burying behavior and increasing exposure to predators.

Aventis' response:

A reference for this statement should be added.

***EFED Response**:*

EFED concurs with the registrant's comments and the appropriate literature citation, i.e., Pozorycki, 1999, has been added.

Page: 11, Paragraph: 2, Line: 7

EPA comment:

In a mesocosms study, at carbaryl…

Aventis' response:

Typographical error. Change to "In a mesocosm study, at carbaryl…"

***EFED Response**:*

EFED concurs with the registrant's comments and the singular form of the noun has been used.

Terrestrial Organisms

Page: 12 Paragraph: 2

EPA comment:

(use of rock dove LD50)

Aventis' response:

The reference cited for this value in Table 1 of Appendix D is currently not available to Aventis. Table 1 of Appendix D gives a range of 1000 – 3000 mg/kg for the LD_{50}. It should be assured that 1000 is indeed the correct value.

***EFED Response**:*

The reference, i.e., Hudson, R. H., R. K, Tucker, and M. A. Haegele. 1984. Handbook of toxicity of pesticides to wildlife. U.S. Department of Interior, Fish and Wildlife Service Resource Publication 153. Washington DC, is routinely cited by EFED. The acute toxicity value (LD_{50} =1,000 mg/Kg) cited for rock dove represents the lower 95% confidence interval. The text has been revised to note that this number represents the lower 95% confidence interval.

Page: 12 Paragraph: 3 Line: 3 - 6

EPA comment:

On a chronic basis, the NOAEC is 300 ppm for the mallard duck, based on adverse reproduction effects, including reduced egg production, decreased fertility, increase incidence of cracked eggs, increased embryonic mortality, and reduced hatching success.

Aventis' response:

The sentence should be changed. The embryonic mortality and the hatching success were not different from the control.

***EFED Response**:*

Although the data evaluation record for the avian reproduction study lists increased embryonic mortality and reduced hatching success as significant effects, reference to these two effects has been deleted from the text since the original study by Fletcher was not available for secondary review. However, reduced egg production, increased incidence of cracked eggs and decreased fertility are reproductive effects that support EFED's concerns regarding the endocrine disrupting potential of carbaryl.

Page: 13 Paragraph: 1 Line: 1

EPA comment:

…(rat LD_{50} = 307 mg/kg)

Aventis' response:

Typographical error, the LD_{50} is 301 mg/kg.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "(rat LD_{50} = 301 mg/L) . . ."

Page: 13 Paragraph: 1 Line: 2 – 4

EPA comment:

…based on decreased fetal body weights and increased incomplete ossification of multiple bones in the laboratory rat (LOAEC = 600 ppm, NOAEC = 80 ppm), has the potential for mammalian chronic effects.

Aventis' response:

A new chronic reproduction study in rats has been submitted by Aventis. This study is more relevant for an ecological risk assessment than the developmental study cited. The new study resulted in a NOAEC of 75 ppm.

***EFED Response**:*

At the time the ecological risk assessment was written, the more recent chronic mammalian toxicity data were not available for EFED to review. The difference in NOAEC would not likely impact the magnitude of the chronic risk quotient though.

Page: 13 Paragraph: 3 Line: 1

EPA comment:

Information available in the open literature suggests potential reproduction effects of carbaryl on mammals.

Aventis' response:

The sentence should be changed or deleted. The literature cited in the paragraph show ambivalent results. While some references seem to support that sentence, other references do not substantiate such a claim. The potential for reproductive effects in mammals is evaluated in the recently submitted 2-generation study in rats. No reproductive effects were seen in that guideline study. The NOAEC of 75 ppm was based on pup mortality.

***EFED Response**:*

EFED believes that the chronic effects cited, i.e., reduced reproduction, disturbances in spermatogenesis, increased resorption of embryos, increased incidence of infertility in females and underdeveloped testes in males, are serious reproductive effects that support EFED's concerns regarding the endocrine disrupting potential of carbaryl.

Page: 13 Paragraph: 4 Line: 5

EPA comment:

According to surveys conducted by the American Beekeeping Federation and the Washington State Department of Agriculture, carbaryl is one of the pesticides most frequently mentioned as being associated with bee kills.

Aventis' response:

A reference should be provided for this statement.

***EFED Response**:*

EFED concurs with the registrant's comments and two literature citations, i.e., Brandi 1997 and Johansen 1997, have been inserted into the text.

Page: 14 Paragraph: 4 Line: 1-4

EPA comment:

The uses of carbaryl on crops (corn, cotton, soybeans, sorghum, wheat, barley, oats, and rye), forests and pasture/rangeland were addressed by the US Fish and Wildlife Service (USFWS) in the reinitiation of consultation in September 1989. The Service found jeopardy to a total of 86 species – 6 amphibians, 47 freshwater fish, 27 freshwater mussels, and 5 aquatic crustaceans.

Aventis' response:

The use of carbaryl on barley, oats, rye, and cotton has been cancelled. It should be noted that all Aventis CropScience labels for the technical materials and the end-use products containing carbaryl were amended to delete these uses. The Agency has already approved the labeling changes. Findings from the assessment made by the USFWS should be reevaluated considering the cancellation of the use on barley, oats, rye, and cotton.

***EFED Response**:*

EFED does not have the resources to continually revise ecological effects assessments each time mitigation efforts have been reached; however, the chapter has been revised to read " . . . on field crops (corn, soybeans, sorghum wheat) . . .."

Page: 14 Paragraph: 5 Line: 7

EPA comment:

The RPAs and RPMs in the 1989 B.O. may need to be reassessed…

Aventis' response:

The acronyms used should be explained.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "Reasonable and Prudent Alternatives (RPA) . . . Reasonable and Prudent Measures (RPM) . . .." The acronym B.O. has been replaced with the term Biological Opinion.

Endocrine Disruption Concerns

Page: 15 Paragraph: 3

EPA comment:

(Report on potential endocrine effects)

Aventis' response:

The paragraph should be deleted. As EPA pointed out, the findings reported in the literature were made at concentrations well above the highest peak concentration modeled. Therefore these findings are irrelevant for a risk assessment and at the current stage of discussion about endocrine disruption. If the concern about the endocrine potential of carbaryl persists, the issue should be revisited once the Agency's endocrine disrupter screening and testing program, as well as a policy on how to incorporate positive findings into an ecological risk assessment have been fully developed.

***EFED Response**:*

The ecological risk assessment reports on a broad range of chronic effects in both terrestrial and aquatic animals that support EFED's concerns regarding the endocrine disrupting potential of carbaryl. EFED is aware of the fact that its current chronic toxicity tests may not be sensitive indicators of endocrine disrupting effects, therefore the Agency has to rely on open literature to address this uncertainty. EFED agrees that some effects are reported at concentrations that may not be environmentally relevant; however, the data suggest that carbaryl can elicit effects that are consistent with a chemical acting on endocrine-mediated pathways. Therefore, EFED is requesting that once appropriate methodologies have been defined for screening endocrine disruption effects, carbaryl should undergo such testing.

Page: 15 Paragraph: 4

EPA comment:

Furthermore, a number of field and laboratory studies report reproduction effects with mammals, suggesting that the possibility of endocrine disruption effects on wild mammals should be further examined.

Aventis' response:

The statement should be deleted or modified. As pointed out above, reports on reproductive effects of carbaryl in the open literature are at least ambivalent. The recently submitted 2-generation study in rats demonstrated the absence of reproductive effects. If the general statement about the potential for endocrine disruption of carbaryl is maintained, references (or a cross-reference within the document) for the above claim should be provided.

***EFED Response**:*

As stated previously, chronic reproductive tests have resulted in effects that support EFED's concerns regarding the endocrine disrupting potential of carbaryl. Just because one study failed to show similar effects to another, EFED does not believe that it would be reasonable to discount the validity of the earlier study. If anything, the data strongly suggests that additional data are needed to better understand the likelihood of adverse effects. Furthermore, carbaryl should be subjected to tests specifically designed to address whether the chemical is acting through endocrine-mediated pathways.

Uncertainties

Page: 15 Paragraph: Last Line: 4

EPA comment:

In the absence of a valid two-generation rat reproduction study, mammalian chronic RQs were based on a rat prenatal development study NOAEC (MRID# 44732901).

Aventis' response:

A new two-generation study in rats was recently submitted.

EFED Response:

As mentioned previously, the most recent two-generation reproduction study of rats was not available for review when the risk assessment was written; however, the proposed difference in the NOAEC, i.e., 75 vs 80, would not significantly impact the magnitude of the chronic mammalian risk quotients nor would it alter the fact that significant effects were noted in the developmental study. However, the text has been revised to read "Additionally, mammalian chronic RQs were based on a rat prenatal development study NOAEC (MRID# 44732901) rather than the more traditional use of a 2-generation reproduction study."

4.0 Environmental Fate Assessment

Exposure Characterization

Page: 16 Paragraph: 3 Line: 8

EPA comment:

Environment (K_f =1.7 to 3.2).

Aventis' response:

The upper value K_f for carbaryl should be listed as 3.5 as referenced by EPA elsewhere in the document (e.g. Table 3, page 20).

EFED Response:

EFED concurs with the registrant's comments and the test has been revised to read "K_f = 1.7 to 3.7".

Page: 16 Paragraph: 3 Line: last sentence

EPA comment:

Detailed discussion and reviews (DERs) of the studies that are included in this assessment are attached in Appendix A.

Aventis' response:

It is inappropriate to include the DERs in the RED.A summary of study findings is already included in the EFED Chapter. DERs should be made available to the public through the regular procedure under the Freedom of Information Act after they have been reviewed and cleared for confidential business information.

***EFED Response**:*

EFED concurs with the registrant's comments that DERs should be made available to the public under the Freedom of Information Act after they have been reviewed and cleared for confidential business information.

Page: 16 Paragraph: 4 Line: 4

EPA comment:

lower levels (generally less than 0.01 µ/L).

Aventis' response:

value missing units - (generally less than 0.01 µ**g**/L).

***EFED Response**:*

*EFED concurs with the registrant's comments and has revised the text to read "0.01 µ**g**/L".*

Page: 16 Paragraph: 5 Line: 4

EPA comment:

…monitoring data is of limited utility in developing EECs for ecological and human health risk assessment.

Aventis' response:

The drinking water monitoring program conducted by the registrant provides a real world assessment of the potential for human exposure to carbaryl in drinking water derived from surface water. Drinking water concentrations derived from PRZM/EXAMS greatly overestimate the potential exposure to carbaryl in drinking water, generally by several orders of magnitude.

***EFED Response**:*

The limitations of the monitoring studies are discussed within the chapter and provide sufficient detail to support EFED's contention that "Because of the limited amount of data available and because of potential problems with extant data . . . monitoring data are of limited utility in developing EECs for ecological and human health risk assessment."

Page: 17 Paragraph: 1 Line: 2-3

EPA comment:

The maximum rate was taken from the carbaryl labels.

Aventis' response:

It would be of benefit for the Agency to be explicit and list the carbaryl labels that were used to develop the maximum application rates for the model scenarios. The reference cited in the EFED Chapter regarding the use of carbaryl on crops indicates that current labels were not used for the Agency's assessment. Many of these crops have been deleted from Aventis' labels for a few years Application

rates, number of applications per season, and PHI's also have changed for several crops on the labels.

***EFED Response**:*

While EFED agrees that additional details are of interest to some readers, it isn't possible to address all potential interests concurrently and still have a reasonably sized document. As noted in the chapter "Average and maximum reported rates were determined by BEAD [Biological and Economic Assessment Division] based on data collected by Doane surveys and registrant market analysis."

Page: 17 Paragraph: 2 Line: 2

EPA comment:

For the Index Reservoir scenario using maximum label rates, acute EEC values ranged from about 10 µg/L from sugar beets to about 500 µg/L from citrus (Table 6).

Aventis' response:

Table 6 on page 33 shows a concentration of 19 µg/L for sugar beets treated with the maximum label rate of 2 x 1.5 lb ai, not 10 as stated in this sentence. A low EEC value of 9 µg/L for sugar beets results from the "maximum reported" application scenario of 1 x 1.2 lb ai/A.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read ". . . acute EEC values ranged from about 19 :g/L from sugar beets to about 500 :g/L . . .."

Page: 17 Paragraph: 2 Line: 3

EPA comment:

Chronic EECs ranged from about 1 to 28 µg/L.

Aventis' response:

Table 6 on page 33 shows that this is correct when considering all of the model scenarios. However, either the same maximum label rate reference should be used as in the preceding sentence (in which case the minimum chronic EEC would be 2), or the basis for the preceding sentence should be changed from the maximum label rate to include all application scenarios to keep the comparisons consistent.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "Chronic EECs ranged from about 2 to 28 :g/L."

Page: 17 Paragraph: 2 Line: 8

EPA comment:

The results of the modeling provide an (sic) conservative, though not unreasonable, estimate on (sic) possible concentrations [in] drinking water.

Aventis' response:

It should be clear that Aventis' surface water monitoring program provides a more reasonable estimate of the potential drinking water exposure to carbaryl than the modeling numbers, which overestimate exposure by several orders of magnitude.

***EFED Response**:*

The limitations of this study are discussed in the chapter.

Page: 17 Paragraph: 2 Line: last

EPA comment:

…and model input and output files are attached in appendix B.

Aventis' response:

The PRZM input files for only the Index Reservoir drinking water modeling were provided as an electronic copy. The PRZM input files for the standard pond scenarios were not provided in the draft RED so Aventis could not assess the data. None of the output files were provided.

***EFED Response**:*

EFED concurs with the registrant's comments; a more comprehensive set of input files have now been included in the chapter (Appendix F).

Page: 18 Figure 2

EPA comment:

Figure 1. Generalized carbaryl degradation pathway

Aventis' response:

This should be labeled Figure 2, not Figure 1.

***EFED Response**:*

EFED concurs with the registrant's comments and the figure entitled Generalized carbaryl degradation pathway has been renumbered Figure 2

Page: 19 Table 3

EPA comment:

Hydrolysis half-life at pH 9 stated to be 5 hours.

Aventis' response:

The study results, and the summary of the study presented on page 20, show the correct half-life at pH 9 to be 3.2 hours.

***EFED Response**:*

EFED concurs with the registrant's comments and the hydrolysis half-life reported for pH in Table 3 has been revised to read 3.2 hours.

Page: 19 Table 3

EPA comment:

Aerobic Aquatic half-life - 4.9.

Aventis' response:

The Aerobic Aquatic half-life is 4.9 days

***EFED Response**:*

EFED concurs with the registrant's comments and the aerobic aquatic metabolism half-life reported in Table 3 has been revised to read 4.9 days.

Page: 19 Table 3

EPA comment:

Soil metabolism $T_{1/2,}$ anaerobic, assumed stable

Aventis' response:

If this guideline is satisfied by the data submitted for guideline 162-3, it is not clear why the compound is assumed to be stable rather than having a half-life in line with the 72 days that resulted from the anaerobic aquatic study. Although this parameter plays a fairly insignificant role in estimating the amount of carbaryl available for runoff in the models, it could play a significant role if one were to use this value in estimating leaching potential in subsurface horizons.

***EFED Response**:*

EFED concurs with the registrant's comments and anaerobic soil metabolism half-life reported in Table 3 has been revised to read 72 days. This does not significantly change the model results.

Page: 20 Table 3

EPA comment:

Batch Equilibrium

1/n values ranged from 0.86-1.02

Aventis' response:

These values are for the desorption isotherms only. For the adsorption isotherms that were used to calculate the adsorption K_f and K_{oc} values listed in the table, the correct range of 1/n values are 0.78 to 0.84 as stated on page 22.

***EFED Response**:*

EFED concurs with the registrant's comments and the batch equilibrium 1/n value range reported in Table 3 has been revised to read 0.78 to 0.84.

Page: 20 Table 3

EPA comment:

Foliar Dissipation

30 days Willis and McDowell, 1987

Aventis' response:

The foliar dissipation half-life listed by EFED is incorrect. Table IV of the Willis and McDowell review lists 10 foliar half-lives for various formulations of carbaryl applied to different crops. Five of these half-lives are for a study designed to evaluate a new analytical procedure for measuring carbaryl residues on plants. This study was conducted on plants grown in a greenhouse, with some of them receiving an unknown amount of simulated rainfall. These studies on greenhouse-grown plants should not be used to evaluate foliar persistence in the field. The foliar persistence of pesticides can be considerably different for residues on and in plants grown in greenhouses versus the field. Eliminating the half-lives for the greenhouse-grown plants results in the following half-lives for carbaryl on field

plants: Cotton, 1.2, 1.3, 1.5 days; strawberry, 4.1 days; tomato 1.4 days. Therefore, the longest half-life of 4.1 days should be listed in this table.

Aventis intends to conduct a more thorough review of the data on the foliar dissipation of carbaryl and prepare a more detailed response during the 60-day public comment period.

***EFED Response**:*

EFED has reviewed the Willis paper and agrees that the foliar dissipation rate for carbaryl is not well known and may be significantly shorter then the default value used. However, as defined in EFED policy, the default value is used when scientifically valid, statistically robust data are not available to make a more accurate estimation. EFED encourages development of better data to justify using a different value.

Persistence

Microbially-Mediated Processes

Page: 21 Paragraph: 3 Line: 3

EPA comment:

with an initial concentration of 11.2 mg/L, degraded with a half-life of 4.0 days in sandy

Aventis' response:

The units for ppm soil concentration should be given as mg/kg.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "11.2 mg/kg".

Page: 21 Paragraph: 3 Line: 4-5

EPA comment:

The major degradate was 1-naphthol which further degraded rapidly to non-detectable levels within 14 days.

Aventis' response:

The data from this study demonstrate that under aerobic soil conditions the formation and decline of 1-naphthol, starting from parent carbaryl is complete in less than 14 days. The study data show an average maximum 1-naphthol level of 34.5% of applied carbaryl by day 1, declining to 2.8% by day 2, 0% by day 4, 0.2% by day 7 and 0% at day 14. These data suggest a preliminary half-life of less than 1 day for the major degradate 1-naphthol.

***EFED Response**:*

EFED agrees that the pattern of formation and decline suggests that 1-naphthol degrades rapidly. However, from the data it is not possible to calculate a valid half-life for 1-naphthol degradation. There are too many processes (formation and degradation, sorption and desorption for example) to permit solving the multiple differential equations for the different rate constants.

Page: 21 Paragraph: 3 Line: 8-9

EPA comment:

In anaerobic aquatic soil carbaryl with an about 10 mg/L degraded with a half-life of 72.2 days.

Aventis' response:

Several words appear to be missing from this sentence. One suggestion: "Carbaryl degraded with a half-life of 72.2 days in anaerobic aquatic sediment with an initial carbaryl concentration of about 10 mg/L."

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "Carbaryl degraded with a half-life of 72.2 days in anaerobic aquatic sediment with an initial carbaryl concentration of about 10 mg/L; 1-naphthol was the major degradate."

Page: 22 Paragraph carried over from page 21 Line: 4 on pg 22

EPA comment:

Chudhry and Wheeler, 1988

Aventis' response:

This reference is not included in the reference list

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "Chaudhry et al., 1988. The references section has been revised to include "Chaudhry, G. R., A.N. Ali, and W.B. Wheeler, 1988. Isolation of a methyl parathion_degrading Pseudomonas sp. that possesses DNA homologous to the opd gene from a Flavobacterium sp. Appl. Environ. Microbiol., 54:288_293.

Mobility

Page: 22 Paragraph: 1 Line: 1

EPA comment:

Carbaryl is considered to be mobile to very mobile in soils.

Aventis' response:

See response directly below.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "Carbaryl is considered to be moderately mobile in soils."

Page: 22 Paragraph: 3 Line: 1-2

EPA comment:

Based on batch equilibrium experiments (*MRID* 43259301) carbaryl was determined to be very mobile to mobile in soils.

Aventis' response:

The classification of carbaryl as mobile to very mobile is inconsistent with measured K_{oc} values of 177 to 249. According to the widely used classification scheme of McCall, *et al.* (1980) wherein K_{oc} values between 150 and 500 denote medium mobility in soil, carbaryl would be classified as having medium mobility in most soils. This classification of medium mobility is further supported by the acceptable column leaching study (MRID 43320701) in which aged carbaryl residues were only slightly mobile in a number of soils. The mobility of carbaryl would be expected to be higher in sandy soils or in soils of low organic matter.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "Based on batch equilibrium experiments (MRID 43259301) carbaryl was determined to be moderately mobile to mobile in soils."

Field Dissipation

Page: 22 Paragraph: 5 Line: 3

EPA comment:

The submitted field and aquatic dissipation studies were determined to be unacceptable, and did not provide useful information on movement and dissipation of carbaryl or its degradation products.

Aventis' response:

The field dissipation study (MRID 41982605) submitted in 1991 demonstrated that carbaryl dissipated very rapidly ($t_{1/2}$ < 1 week) with no measurable leaching. The study included two sites, one in North Carolina and one in California. At the North Carolina site, ~ 95% of the Time 0 residues had dissipated by the first sampling period 7 days after application (the planned first sampling at 3 days was not collected due to rain). Similarly, ~ 85% of the Time 0 residues had dissipated by 7 days after application at the California site. Concerning the

movement of carbaryl, samples were taken to a depth of 0.9 meters in increments of 0.15 meters. No residues were found below the upper 0.15 meters.

***EFED Response**:*

This field dissipation study (MRID 41982605) was reviewed and determined to be scientifically invalid. As described in the text, these studies do not provide reliable information on the rate of dissipation of parent carbaryl or formation of degradation products because of inappropriate sampling intervals, poor sample storage stability, lack of degradate monitoring, rainfall and irrigation that were less than evapotranspiration, and irrigation water with high pH. The registrant is required to conduct additional studies and submit new data. When the studies have been reviewed and determined to be acceptable, the data will be incorporated into future assessments.

Page: 23 Paragraph: 3 Line: 2

EPA comment:

Because of inappropriate sampling intervals, poor sample storage stability, lack of degradate monitoring, rainfall and irrigation that were less than evapotranspiration, and irrigation water with high pH, these studies do not provide reliable information on the rate of dissipation of parent carbaryl or formation of degradation products.

Aventis' response:

The estimated half-life determined from this study was < 3 days. Sampling at intervals such that several sampling events are taken prior to the half-life of the product is impractical for rapidly degrading chemicals (e.g., those with half-lives less than a week). For this rapidly degrading chemical an estimate of the half-life should be sufficient for risk assessments even if it is not precise.

After the report was submitted to California, the freezer storage stability recoveries at six and nine months were measured but not reported. Rainfall plus irrigation approximated an inch a week and was more than enough to maintain a good soil moisture for agricultural purposes.

Sulfuric acid is routinely added to irrigation water in the region of California where the field test was conducted to neutralize the water's high pH. Although not stated in the report, the irrigation water in the California trial was treated in the typical commercial fashion. The acid is injected into the irrigation pipe as water is pumped through it. Unfortunately, the pH of the water arriving at the field after treatment was not measured.

***EFED Response**:*

As discussed in the preceding response, the terrestrial field dissipation study was reviewed and determined to be scientifically invalid. The registrant is required to conduct additional studies and submit new data. When the studies have been completed and reviewed and determined to be acceptable the data will be incorporated into future assessments.

Aquatic Field Dissipation

Page: 24 Paragraph: 2 Line: 3

EPA comment:

They (do) not provide useable information on the dissipation of carbaryl and 1-naphthol in aquatic field conditions.

Aventis' response:

The soil metabolism study referred to in the report found that the total water soluble metabolites did not exceed 5% of the total radioactive residue, the primary hydrolysis product, 1-naphthol, was not found, and that the only analyte of concern was the parent insecticide, carbaryl. A soil metabolism study reviewed concurrently by the Agency was issued later (MRID 42785101, classified "acceptable") with similar results. Although the major soil metabolite, 1-naphthol, was found at significant levels at day 0 and day 1, the levels were less than 0.7% by day 4 and non-detectable by day 14. Two other metabolites were identified but never exceeded levels of 1.7% of the total residue. Again the only residue of concern was the parent insecticide, carbaryl.

If present, 1-naphthol would have been detected by the residue method used to measure the residues of carbaryl in the soil.

The estimated half-life determined from this study was < 2 days. Sampling at intervals such that several sampling events are taken prior to the half-life of the product is impractical for rapidly degrading chemicals (e.g. those with half-lives less than a week).

EFED Response:

The aquatic field dissipation study was reviewed and determined to be unacceptable since it did not provide useable information on the dissipation of carbaryl and 1-naphthol under aquatic field conditions. The registrant is encouraged to conduct additional studies and submit new data. In future studies sampling intervals should be selected that are appropriate for the expected half-life. When the studies have been reviewed and determined to be acceptable the data will be incorporated into future assessments.

Page: 24 Paragraph: 2 Line: 4

EPA comment:

Frozen storage stability data were provided for only 6 months, although the water samples were stored for up to 14 months and the soil samples were stored for up to 17.5 months prior to analysis. The data suggest that carbaryl and 1-naphthol degraded significantly during storage. In the six months of storage carbaryl degraded an average of 34 % in Texas water and 39% in from Mississippi. 1-naphthol degraded 50% in water from Texas and 69% from Mississippi. Degradation did not appear linear, and it is not possible to extrapolate out to 14 months. It was therefore not possible to evaluate the actual concentrations of carbaryl and 1-naphthol in the samples or estimate the dissipation rates.

Aventis' response:

The existing 6-month storage stability provides sufficient information to calculate the concentrations of carbaryl in the samples. However, the metabolite 1-naphthol was shown to degrade significantly under the same freezer conditions. This instability simply confirms that 1-naphthol's presence in the environment would be very limited and should not be of concern.

EFED Response:

As discussed in the preceding response, the aquatic field dissipation study was classified as unacceptable. Degradation did not appear to be linear, and it is not possible to extrapolate out to 14 months; therefore it is not possible to evaluated the actual concentrations of carbaryl and 1-naphthol in the samples or estimate the dissipation rates.

Foliar Dissipation

Page: 24 Paragraph: Last

EPA comment:

The reported rates of carbaryl dissipation from foliar surfaces varies from 1 days to 30 days. In their review of literature data on pesticide foliar persistence, Willis and McDowell (1987) report that carbaryl dissipation rates varied from 1.2 to 29.5 days… For terrestrial risk assessment modeling EFED used 35 days…

Aventis' response:

As stated in comments to Table 3, the foliar dissipation half-life used by EFED for terrestrial risk assessment is too long and should be corrected. Table IV of the Willis and McDowell review lists 10 foliar half-lives for various formulations of carbaryl applied to different crops. Five of these half-lives are for a study designed to evaluate a new analytical procedure for measuring carbaryl residues on plants. This study was conducted on plants grown in a greenhouse, with some of them receiving an unknown amount of simulated rainfall. These studies on greenhouse-grown plants should not be used to evaluate foliar persistence in the field. The foliar persistence of pesticides can be considerably different for

residues on and in plants grown in greenhouses versus the field. Eliminating the half-lives for the greenhouse-grown plants results in the following half-lives for carbaryl on field plants: Cotton, 1.2, 1.3, 1.5 days; strawberry, 4.1 days; tomato 1.4 days. Therefore, the longest half-life of 4.1 days should be used for terrestrial risk assessment modeling.

Aventis will conduct a more thorough review of the data on the foliar dissipation of carbaryl and prepare a more detailed response during the 60-day public comment period.

***EFED Response**:*

EFED agrees that the dissipation of carbaryl on foliar surfaces is not well understood. The registrant is encouraged to submit additional data on foliar dissipation to help clarify the rate and processes involved. Until scientifically valid, statistically robust data are submitted, EFED policy is to use a default value of 35 days and assume first order degradation kinetics.

Atmospheric Transport

Page: 25 Paragraph: 1 Line: 2

EPA comment:

Waite, *et al.*, 1995

Aventis' response:

This reference is not included in the reference list

***EFED Response**:*

EFED concurs with the registrant's comments. The reference section has been revised to include the following reference: Waite, D.T., R. Grover, N.D. Westcott, D.G. Irvine, L.A. Kerr and H. Sommerstad, 1995. Atmospheric Deposition of Pesticides in a Small Southern Saskatchewan Watershed. Environ. Toxicol. and Chem., 14:1171-1175.

Page: 25 Paragraph: 1 Line: 3

EPA comment:

Beyer *et al.*, (1995)

Aventis' response:

This reference is not included in the reference list

***EFED Response**:*

EFED concurs with the registrant's comments. The reference section has been revised to include the following reference: Beyer, D.W., M.S. Farmer and P.J. Sikoski, 1995. Effects of rangeland aerial application on Sevin-4-Oil® on fish and aquatic invertebrate drift in the Little Missouri River, North Dakota. Arch. Environ. Contam. Toxicol., 28:27-34.

Page: 25 Paragraph: 3 Line: 5

EPA comment:

Schomburg *et al.* (1991)

Aventis' response:

This reference is not included in the reference list

EFED Response:

EFED concurs with the registrant's comments. The reference section has been revised to include the following reference: Schomburg, C.J., D.E. Glotfelty, and J.N. Seiber, 1991. Pesticide occurrence and distribution in fog collected near Monetery California. Environ. Sci. Technol. 25:155-160.

1-Naphthol Fate and Transport

Page: 26 Paragraph: 2 Line: 1-2

EPA comment:

In an aerobic soil metabolism study (MRID 42785101), 1-naphthol degraded rapidly to non-detectable levels within 14 days.

Aventis' response:

The data from this study demonstrate that under aerobic soil conditions the formation and decline of 1-naphthol, starting from parent carbaryl, is complete in less than 14 days. The study data show an average maximum 1-naphthol level of 34.5% of applied carbaryl by day 1, declining to 2.8% by day 2, 0% by day 4, 0.2% by day 7 and 0% at day 14. These data suggest a preliminary half-life of less than 1 day for the major degradate 1-naphthol. This half-life can be used for preliminary environmental fate modeling to estimate EECs for 1-naphthol.

EFED Response:

As stated previously, it is not possible to separate the multiple processes occurring in this study, and it is not possible to calculate rate constant for degradation of 1-naphthol. Additional data on the degradation of 1-naphthol are required.

Page: 26 Paragraph: 3 Line: 1

EPA comment:

No guideline information was submitted on 1-naphthol sorption. Literature information suggests that it is not strongly sorbed.

Aventis' response:

The statement suggesting that 1-naphthol is not strongly sorbed to soil should be deleted. In support of the 1-naphthol sorption statement the Agency has cited only one paper by Karthikeyan *et al.* (1999) that was conducted using aluminum hydroxide as the sorbent. Soil is composed of much more than aluminum hydroxide, so this study is more of a mechanistic description of sorption to this one component of soil and not a study of sorption to soil as a whole. This cited study reported that 1-naphthol does not show significant sorption to aluminum hydroxide when allowed to sorb for 20 hours in the dark in the absence of oxygen. However, there was a significant increase in sorption with increasing equilibration time, and as the Agency stated, the increase is influenced by pH, as would be expected for an acidic phenolic compound.

Additional information available in the literature demonstrates that the sorption of 1-naphthol to soil is stronger than that seen for carbaryl itself. Hassett *et al.* (1981) have demonstrated that the sorption of 1-naphthol was the result of sorption to organic carbon resulting in an average K_{oc} of 431 ± 40 for 10 of the 16 soil samples they tested. In the remaining 6 soil samples the K_{oc} was even higher (1,645 to 15,618). Hassett *et al.* (reference submitted as part of 30-day response document) hypothesized that the higher K_{oc}s in these 6 soils, in which the organic carbon to clay ratio was very low, the clay surfaces were more accessible and the sorption of 1-naphthol was apparently controlled by the clay fraction. In Burgos *et al.* (1999), cited by EPA elsewhere in the RED, it was shown that there is significant sorption of 1-naphthol to two sandy soils, and that oxidative coupling reactions were responsible for the strongly bound portion. In an earlier paper by Burgos *et al.* (1996) it was shown that both biologically-mediated and soil-catalyzed oxidative coupling lead to significant binding of 1-naphthol residues to soil. These data indicate that 1-naphthol is less mobile and less susceptible to leaching than carbaryl itself, and they demonstrate that at least a portion of the 1-naphthol residue is tightly sorbed to soil constituents.

To meet the requirement by the Agency for information on the adsorption and desorption of 1-naphthol, the registrant is conducting an adsorption/desorption study to meet the 163-1 guideline. Study results should be available for submission to the Agency in the first quarter of the calendar year 2002.

EFED Response:

Data from the Hassett paper have been included. The text reads "Hassett et al. (1981) reported an average 1-naphthol K_{oc} of 431 (± 40) for 10 of the 16 soils tested. They also found that in other soils with very low organic carbon to clay ratios clay surfaces controlled sorption. Additional data on

1-naphthol sorption is required to fully characterize mobility." Additional data will be reviewed and incorporated into future risk assessments.

Aquatic Exposure Assessment

Surface Water

Page: 26 Paragraph 4 Line 1

EPA comment:

Five crop scenarios: apples, field corn, sweet corn, oranges and sweet potatoes scenarios were use in modeling for surface water EEC.

Aventis' response:

The fifth crop modeled was sugar beets (not sweet potatoes).

***EFED Response**:*

EFED concurs with the registrant's comments. The text has been revised to read "Five crop scenarios: apples, field corn, sweet corn, oranges and sugar beets scenarios were used in modeling for surface water EEC."

Page: 27 Table 4

EPA comment:

Hydrolysis half-life at pH 9 stated to be 5 hours.

Aventis' response:

The study results, and the summary of the study presented on page 20, show the correct half-life at pH 9 to be 3.2 hours.

***EFED Response**:*

EFED concurs with the registrant's comments. The hydrolysis half-life at pH 9 reported in Table 4 has been revised to read "3.2 hours".

Page: 27 Table 4

EPA comment:

(K_{oc} = 211 for SCIGROW)

Aventis' response:

This is the mean K_{oc}. According to EPA guidance the median K_{oc} (209) should be used for SCI-GROW, although this difference would not be expected to affect the model results.

***EFED Response**:*

EFED concurs with the registrant's comments. The mean soil partitioning coefficient (Koc) reported in Table 4 now reads "(K_{oc} = 209 for SCIGROW)".

Pages: 27-28 Table 5

EPA comment:

Tier II surface water estimated environmental concentration (EEC) values derived from PRZM/EXAMS modeling for use in ecorisk assessment (calculated using standard pond.)

Aventis' response:

The PRZM input tables were not provided for the standard pond scenarios, so the assumption is made that the same application methods were used for the standard pond as for the Index Reservoir scenarios that were provided as an electronic copy of a draft of Appendix B.

***EFED Response**:*

The registrant's assumption is correct, i.e., the same application methods were used for the standard pond as for the Index Reservoir scenarios.

Aventis' comment:

It would be of benefit for the Agency to state which of the carbaryl labels were used to develop the "maximum" label application rate scenarios. It would be useful to add another column to this table to specify which method of application was used to generate the EECs rather than the generic "air/ground" in column 1. There are a number of errors in the input parameters (noted below) that would lead to changes in the calculated EECs and therefore the risk quotients for these uses.

***EFED Response**:*

EFED has reviewed the application rates used in modeling. The changes suggested by the registrant do not result in significant changes in the risk assessment; therefore, the modeling was not redone. As with most chemicals, the labels are in a constant state of flux. Uses are dropped and rates varied constantly. Also this chemical has a large number of labels making it difficult for EFED to monitor the changing "current" labels.

The use of average use rates was to allow evaluation of EECs based on rates other then the maximum allowed. The data that were used to calculate "average" are not highly robust. It is also not always possible to use the values in the Quantitative Use Assessment (QUA) as presented. For example the average number of applications for sugar beets was 1.1 per year. EFED selected rates and timing to try to capture the information in the QUA table. The values should nor be considered hard, exact numbers.

If the modeling for the "average" scenarios were conducted using aerial applications for citrus and apples (as was the case for the Index Reservoir scenarios), then the model results over-estimate the contributions from spray drift. Few applications to these crops are made aerially. Therefore, the model results over-estimate the contributions from spray drift since the "average" applications to these crops are made using ground airblast equipment with a spray drift of 6.3% in the model versus aerial applications with a spray drift of 16%.

The "average" scenario for sweet corn in Ohio should be 3 applications at 1.1 lb. ai/A/application (as noted in the memo, "Average application rate from Quantitative Usage Analysis for Carbaryl, prepared July 21, 1998 by Frank Hernandez, OPP/BEAD") and not the 2 applications at 3.4 lb. ai/A/application as listed in the table. It should be noted that the "average" scenario presented in this table, 2 applications per year at 3.4 lb. ai per application, exceed the maximum rate allowed on the label.

The maximum label rate application scenario for apples that is allowed by the Sevin brand XLR PLUS label (E.P.A. Reg. No 264-333), the Sevin brand 80WSP and CHIPCO Sevin brand 80WSP labels (E.P.A. Reg. No 264-526) and the CHIPCO Sevin brand SL label (E.P.A. Reg. No 264-335) is 5 applications at 3 lb. ai/A/application made every 14 days. The scenario used in the model applies less than the maximum amount of product allowed by the labels. In addition, if the same application timing was used in the modeling for the standard pond scenario as was used in the index reservoir scenario (applications made by air every 4 days) this would be a violation of the Aventis labels which restrict applications to a minimum of every 14 days.

The "average" scenario for sugar beets in Minnesota should be 1 application at 1.3 lb. ai/A/application (as noted in the memo, "Average application rate from Quantitative Usage Analysis for Carbaryl, prepared July 21, 1998 by Frank Hernandez, OPP/BEAD") and not 1 application at 1.5 lb. ai/A/application as listed in the table.

***EFED Response**:*

The Quantitative Use Assessment lists the "average" lb A.I./acre at 1.5 and the average number of applications as 1.1.

The "Citrus" scenario would be more appropriately labeled Oranges. For the average scenario, the 3.4 lb. ai/A/application rate listed in Table 5 is for oranges (as noted in the memo, "Average application rate from Quantitative Usage Analysis for Carbaryl, prepared July 21, 1998 by Frank Hernandez, OPP/BEAD"), which is the highest "average" application rate for any type of citrus. Therefore, this "average" scenario for oranges are at the high end for all citrus and overestimates the PRZM/EXAMS derived EECs for use in the other citrus crops. "Average" application rates for other citrus as listed in the memo are:

Lemons – 1.3 applications at 2.7 lb ai/A/appl
Grapefruit – 1.6 applications at 1.4 lb ai/A/appl
Citrus, other – 1.8 applications at 1.8 lb ai/A/appl

The maximum label application rate for citrus is 7.5 lb ai per application, not 5 lb ai, with a maximum of 20 lb ai total allowed per year. In California only, a single application is allowed at the rate of 5 to 16 lb ai per season for control of California red scale and yellow scale.

***EFED Response**:*

Table 5 has been revised to read "oranges" instead of "citrus".

Estimated Environmental Concentrations for Terrestrial Ecological Risk Assessment

Page: 29 Paragraph: 2 Line:2-4

EPA comment:

In the absence of reliable foliar dissipation data a dissipation half-life of 35 days is used. Published literature shows that carbaryl dissipation rates vary, and are among the highest observed for any pesticide (Willis and McDowell, 1987).

Aventis' response:

As stated in more detail above, some of the foliar dissipation half-lives listed in this reference are high because they were generated in the greenhouse, not in the field, and therefore they should not be used. Eliminating the half-lives for the greenhouse-grown plants results in the following half-lives for carbaryl on field plants: Cotton, 1.2, 1.3, 1.5 days; strawberry, 4.1 days; tomato 1.4 days. Therefore, the longest half-life of 4.1 days should be used for terrestrial risk assessment modeling.

***EFED Response**:*

As in the response provided above, EFED agrees that the dissipation of carbaryl on foliar surfaces is not well known. Until additional data are provided the default value is used.

Page: 29 Paragraph: 2 Line:6

EPA comment:

A more thorough description of the model calculations and ELL-FATE outputs are attached in Appendix B.

Aventis' response:

No such description or attachments were provided, so Aventis did not have the opportunity to evaluate the model.

***EFED Response**:*

EFED concurs with the registrant's comments. A more thorough description of the ELL-FATE model along with copies of its input and output files are contained in Appendix E.

Page: 29 Paragraph: 2 Line:last

EPA comment:

…Tables 4,7, 8 and 9, Appendix D.

Aventis' response:

These tables are in Appendix C.

***EFED Response**:*

EFED concurs with the registrant's comments. The text has been revised to read "EEC values calculated for different crop applications are presented in Tables 4, 7, 8, and 9, Appendix C."

5.0 Drinking Water Assessment

Water Resources Assessment

Page: 29 Paragraph: 3 Line:3

EPA comment:

Carbaryl tends not to partition to soil, aquifer solids, or sediment.

Aventis' response:

This sentence is misleading and should be reworded. Carbaryl does partition onto these sorbents, but the sorption coefficients are not high. Suggest rewording this such as: "Carbaryl tends not to bind tightly to soil, aquifer solids, or sediment."

***EFED Response**:*

EFED concurs with the registrant's comments. The text has been revised to read "Carbaryl tends not to bind tightly to soil, aquifer solids, or sediment."

Page: 29 Paragraph: 4

EPA comment:

Under certain conditions carbaryl can be expected to persist in the environment. Under low pH conditions the compound is stable to hydrolysis. In anaerobic environments metabolism is fairly slow ($t_{½}$ = 72 days). This suggests that carbaryl may leach to ground water and persist in some aquifers.

Aventis' response:

This last statement should be removed. In contrast to this hypothesis are the data presented in the NAWQA and EPA databases that demonstrate that carbaryl is not likely to leach to ground water and is not likely to persist in aquifers. The fact that carbaryl has been widely used in agricultural and urban settings for more than 35 years, and yet is found at concentrations greater than 0.1 µg /L in only 0.027% of the agricultural wells, urban wells and aquifers sampled by NAWQA (Kolpin, 2001), indicates that this statement has little merit. Furthermore, the last sentence is in direct contradiction to the statement made at the beginning of the preceding paragraph that carbaryl "…has limited potential to leach to ground water."

***EFED Response**:*

EFED concurs with the registrant's comments. The last sentence of the paragraph has been deleted and the text reads "Under certain limited conditions carbaryl may be expected to persist in the environment. Under low pH conditions the compound is stable to hydrolysis. In anaerobic environments metabolism is fairly slow ($t_{½}$ = 72 days)."

Page: 30 Paragraph: 1 Lines 1-3

EPA comment:

Surface water monitoring studies show that carbaryl is the second most widely detected insecticide after diazinon. Carbaryl, at typically low concentrations, is found in greater than 20 % of surface samples at concentrations up to 7 ppb.

Aventis' response:

These summary statements are based on the NAWQA database, with the exception of the 7 ppb concentration. The highest reported value in the NAWQA database is 5.5 ppb. The value of 7 ppb does not come from the NAWQA database but from the report by Werner *et al*. (2000). In fact, a maximum carbaryl concentration of 8.4 ppb was reported for surface water samples in the California DPR surface water database (see discussion section). The sources of the information should not be mixed, or the source of the information should be explicitly stated.

***EFED Response**:*

EFED concurs with the registrant's comments. The text has been revised to read "Surface water monitoring studies show that carbaryl is the second most widely detected insecticide after diazinon. Carbaryl, at typically low concentrations, is found in greater than 20 % of surface samples in NAWQA studies at concentrations up to 5.5 ppb. Carbaryl is detected more frequently in non-agricultural areas (about 40%) then in agricultural areas (about 5 %). A maximum carbaryl concentration of 8.4 ppb was reported for surface water samples in the California DPR surface water database. Carbaryl is generally not widely detected in groundwater monitoring studies though some studies have found concentrations of up to several hundred ppb. Concentrations as high as 610 µg/L have been detected in one case but typical groundwater concentrations are much lower. NAWQA

studies have found that about 1 % of groundwater samples have measurable levels (> 0.003 µg/L) of carbaryl, with a maximum concentration of 0.02 µg/L. Targeted studies designed to measure carbaryl in groundwater are not available."

Drinking Water Exposure Assessment

Page: 30 Paragraph: 2 Line:3-4

EPA comment:

Carbaryl is the second most commonly detected insecticide in surface water, and can be expected to contaminate drinking water derived from surface water bodies.

Aventis' response:

The surface water-monitoring program conducted by Aventis shows an insignificant impact of carbaryl on drinking water.

EFED Response:

EFED's interpretation of the surface water-monitoring program conducted by Aventis has been discussed previously in this document.

Page: 30 Paragraph: 2 Line: 7

EPA comment:

The maximum reported value was 7.0 µg /L.

Aventis' response:

The maximum value reported in the NAWQA database is 5.5 µg /L. The only carbaryl detection reported in the study by Werner *et al*. (2000) was 7.0 µg /L. The maximum value reported in the California DPR Surface Water database is 8.4 µg/L. Since all of the statistics made in this paragraph refer to the NAWQA data, the reference to the maximum reported concentration should be 5.5 µg /L.

EFED Response:

EFED concurs with the registrant's comments. The text has been revised to read "The maximum reported value in surface water was 8.4 µg/L."

Page: 30 Paragraph: 4 Line: 2

EPA comment:

Older studies using GC or GC/MS generally have poor recovery and quantitation limits. Because of this difficulty in analysis the actual concentration of carbaryl in groundwater and surface waters may be higher than reported.

Aventis' response:

The basis for making this generalization is not readily apparent and these statements should be removed. Comments regarding the recovery reported for the GC/MS method used in the NAWQA survey are made below in reference to statements made on page 34 paragraph 5, and are elucidated in the discussion section at the end of this response document. The method detection limit (MDL) reported for the GC/MS method used for the NAWQA program is 0.003 ppb (Zaugg *et al*., 1995; Larson *et al.* , 1999). The limit of detection for the HPLC/MS/MS method used in the carbaryl surface water monitoring study being conducted by the registrant (LOD, 0.002 ppb; LOQ 0.030 ppb) is similar to the GC/MS method used for the NAWQA program. In addition to the GC/MS method used in the NAWQA program, carbaryl was also analyzed by HPLC/photodiode-array detection in a limited number of samples with a MDL of 0.008 (Werner *et al*., 1996). Therefore, the quantification limits reported for the GC/MS method used to generate a majority of the carbaryl data in the NAWQA database is very similar to the quantification limits for available HPLC methods. See the discussion section at the end of this response document for a summary of the available NAWQA data obtained by the GC/MS and HPLC/PDA methods.

***EFED Response**:*

EFED has concerns that poor detection limits in the past may have underestimated the concentration of carbaryl in surface and groundwater. However, a sentence has been added to the paragraph stating "More recent studies using HPLC/MS should provide better data on the true extent and magnitude of water contamination from the use of carbaryl."

Page: 30 Paragraph: 4 Line: 4

EPA comment:

More recent studies using HPLC/MS should provide better data on the true extent and magnitude of water contamination from the use of carbaryl.

Aventis' response:

Aventis believes that our ongoing targeted surface water-monitoring program using HPLC/MS/MS accurately reflects the extent and magnitude of carbaryl exposure in drinking water derived from surface water.

***EFED Response**:*

EFED agrees that the ongoing study applies more appropriate analytical methods. The limitations of the study have been discussed elsewhere.

Drinking Water Modeling

Page: 31 Paragraph: carried over from page 30 Line: 8

EPA comment:

A partial list of input parameters for the PRZM/EXAMS modeling are given in Table 4.

Aventis' response:

The partial list of input parameters in Table 4 includes multiple conservative assumptions likely to lead to significant over-estimation of the potential surface water concentrations of carbaryl.

EFED Response:

The modeling was done following EFED policy and standard procedures. EFED concurs with the registrant that the PRZM/EXAMS model includes a number of conservative assumptions.

Page: 31 Paragraph: 2 Line: 1

EPA comment:

For the Index Reservoir scenario using maximum label rates, acute EEC values ranged from 19 µg/L from sugar beets to 494 µg/L for oranges (Table 6).

Aventis' response:

Table 6 on page 33 shows a concentration of 19 µg/L for sugar beets treated with the maximum label rate of 2 x 1.5 lb ai, not 10 as stated in this sentence. A low EEC value of 9 µg/L for sugar beets results from the "maximum reported" application scenario of 1 x 1.2 lb ai/A.

EFED Response:

EFED concurs with the registrant's comment. The text had been revised to present more generalized ranges and reads ". . . acute EEC values ranged from about 10 µg/L from sugar beets to about 500 µg/L from citrus (Table 6)."

Page: 31 Paragraph: 2 Line: 3

EPA comment:

Chronic EECs ranged from about 1 to 28 µg/L.

Aventis' response:

Table 6 on page 33 shows that this is correct when considering all of the model scenarios. However, either the same maximum label rate reference should be used as in the preceding sentence (in which case the minimum chronic EEC would be 2), or the basis for the preceding sentence should be changed from the maximum label rate to include all application scenarios to keep the comparisons consistent.

***EFED Response**:*

EFED concurs with the registrant's comments. The text has been revised and now reads "Chronic EECs ranged from about 2 to 28 µg/L."

Page: 31 Paragraph: 2 Line: 6

EPA comment:

It is highly unlikely that any but the most extensive targeted monitoring would capture the actual peak concentrations.

Aventis' response:

The role of a peak concentration in dietary exposure assessment is undergoing re-examination within EPA. The current policy of EPA appears to define a certain percentile as an appropriate value for use in screening assessments, but the exact percentile to be used is being currently set by EPA management. (The most recent documents from EPA cite the 95th or 99th percentile.) For more comprehensive assessments, a distribution of values is preferred.

***EFED Response**:*

EFED further qualifies its statement by saying "The results of the modeling provide a very conservative, though not unreasonable, estimate of possible concentrations in drinking water. A more detailed assessment of the source of water used to provide drinking water and the relationship between the areas where carbaryl is used and surface water sources is required to more accurately evaluate possible human exposures."

Page: 31 Paragraph: 2 Line: 7

EPA comment:

The results of the modeling provide a conservative, though not unreasonable, estimate on possible concentrations drinking water.(sic)

Aventis' response:

The modeling, performed according to EPA procedures, provides an upper bound estimate on potential concentrations in drinking water from surface water. Whether the modeling estimates are reasonable depends on the specific assumptions. For carbaryl, the three-year monitoring program (conducted according to EPA and ILSI guidance available at the time

the study was started) shows that the model calculations are unreasonable. These conservative assumptions include a 3x factor on both the aerobic soil and aerobic aquatic half lives, assuming the maximum drift rate for aerial applications throughout the county (in Florida citrus almost all applications are by air blast with ground equipment), and the application rate over a watershed. The conservative nature of the application assumption alone probably results in an overprediction by at least two orders of magnitude. The modeling calculations assume an application rate of 17.4 lbs/acre of watershed annually. In Hardee County, the county with the highest usage of carbaryl, the average use rate on a countywide basis is only 0.31 lb/acre (See Appendix II). In Manatee County, the county with the highest usage containing a watershed used to supply drinking water, the average rate on a countywide basis is 0.027 lb/acre.

EFED Response:

EFED concurs with the registrant's comments and as noted in the previous response, the text has been revised and now reads "The results of the modeling provide a [very] conservative, though not unreasonable, estimate of possible concentrations [in] drinking water."

Page: 31 Paragraph: 2 Line: 8

EPA comment:

A more detailed assessment of the source of water used to provide drinking water and the relationship between the areas where carbaryl is used and surface water sources is required to more accurately evaluate possible human exposures.

Aventis' response:

As mentioned by EPA in this document, ground water is the source of the majority of Florida drinking water. Many of the counties with the highest use of carbaryl contain no watersheds used to provide drinking water. As discussed more fully in Appendix I, the watershed supplying the Manatee County Water Treatment Plant appears to have the most carbaryl usage of drinking water watersheds in Florida.

EFED Response:

The registrant's response is expressing their perspective on the likelihood that watersheds in particular areas serve as drinking water sources; the comments do not reflect an error in the EFED risk assessment.

Water Treatment Effects

Page: 31 Paragraph: 3 Line: 8

EPA comment:

Since relatively (sic) few water treatment facilities in the U.S. use ozone the limited data available do not indicate that carbaryl is likely to be degraded in the majority of treatment plants.

Aventis' response:

The monitoring program conducted by the registrant shows that removal occurs in some treatment plants. The effect of treatment seemed to be greater in systems using carbon treatment.

***EFED Response**:*

The design of the water monitoring study does not allow the results to be used to evaluate treatment. For example, raw and treated water samples were not collected from the same mass of water, and treated water was not analyzed for all sampling periods. Treated water was found to have higher concentration in at least one case. The limitations of the study have been discussed elsewhere.

Page: 33 Table 6

EPA comment:

Drinking Water EECs (Table 6 entitled)

Aventis' response:

Many of the comments for this table are similar to those for the EECs for ecological risk found in Table 5.

The PRZM model input parameters for the Index Reservoir scenarios were received as an electronic copy of a draft of Appendix B. These input files are very useful for assessing the scenarios that have been modeled.

It would be useful to add another column to Table 6 to specify which method of application was used to generate the EECs (and thus the application efficiency and spray drift values). It would be of benefit for the Agency to state which of the carbaryl labels were used to develop the "maximum" label application rate scenarios. There are a number of errors in the input parameters (noted below) that would lead to changes in the calculated EECs and therefore the risk quotients for these uses.

The model parameters listed in the electronic draft of Appendix B show that the "average" scenarios for citrus and apples were conducted using aerial applications. Few applications to these crops are made aerially. Therefore, the model results over-estimate the contributions from spray drift since the "average" applications to these crops are made using ground airblast equipment with a spray drift of 6.3% versus aerial applications with a spray drift of 16%.

The "maximum label rate" application scenario for apples that is allowed by the Sevin brand XLR PLUS label (E.P.A. Reg. No 264-333), the Sevin brand 80WSP and CHIPCO Sevin brand 80WSP labels (E.P.A. Reg. No 264-526) and the CHIPCO Sevin brand SL label (E.P.A. Reg. No 264-335) is 5 applications at 3 lb ai/A/application made every 14 days. The scenario used in the model applies less than the maximum amount of product allowed by the labels. In addition, application timing was used in the modeling for the index reservoir scenario (applications made by air every 4 days) that would be a violation of the Aventis labels which restrict applications to a minimum of every 14 days.

The "average" scenario for sweet corn in Ohio should be 3 applications at 1.1 lb ai/A/application (as noted in the memo, "Average application rate from Quantitative Usage Analysis for Carbaryl, prepared July 21, 1998 by Frank Hernandez, OPP/BEAD") and not the 2 applications at 3.4 lb ai/A/application as listed in the table. The PRZM input file shows the correct inputs of 3 applications at 1.1 lb ai/A/application.

The "average" scenario for sugar beets in Minnesota should be 1 application at 1.3 lb ai/A/application (as noted in the memo, "Average application rate from Quantitative Usage Analysis for Carbaryl, prepared July 21, 1998 by Frank Hernandez, OPP/BEAD") and not 1 application at 1.5 lb ai/A/application as listed in the table and the PRZM input file.

The "Citrus" scenario would be more appropriately labeled Oranges. For the average scenario, the 3.4 lb ai/A/application rate listed in Table 5 is for oranges (as noted in the memo, "Average application rate from Quantitative Usage Analysis for Carbaryl, prepared July 21, 1998 by Frank Hernandez, OPP/BEAD"), which is the highest "average" application rate for any type of citrus. Therefore, this "average" scenario for oranges is at the high end for all citrus and overestimates the EECs for use in the other citrus crops. "Average" application rates for other citrus as listed in the memo are:

Lemons – 1.3 applications at 2.7 lb ai/A/appl
Grapefruit – 1.6 applications at 1.4 lb ai/A/appl
Citrus, other – 1.8 applications at 1.8 lb ai/A/appl

EFED Response:

EFED used available data from the Biological and Economic Assessment Division (BEAD) in 2001 to develop the risk assessment. However, the recommended changes would not substantially change EFED's risk assessment; therefore, the table has not been significantly revised other than changing "citrus" to read "oranges".

Ground Water Resources

Page: 34 Paragraph: carried over from page 33 Line:3

EPA comment:

U.S. EPA. Pesticides in Groundwater Database (Jacoby *et al.*, 1992)

Aventis' response:

This reference is not provided in the reference list.

***EFED Response**:*

EFED concurs with the registrant's comments and the reference section has been revised to include the following reference: Jacoby, H., C. Hoheisel, J. Karrie, S. Lees, L. Davies-Hilliard, P. Hannon, R. Bingham, E. Behl,, D. Wells, and E. Waldman, 1992. Pesticides in groundwater database: a compilation of monitoring studies: 1971-1991 National Summary. EPA 734-12-92-001.

Page: 34 Paragraph: 3 Line: 3

EPA comment:

Detections were from (sic) mainly from three use sites: wheat (5.8 % of well samples from wheat land use), orchards and vineyards (1.7 % of well samples from orchard and vineyard land use), and urban (1.8% of urban groundwater samples).

Aventis' response:

Updated information (noted below) is not summarized in the same manner as in this statement, so direct comparisons cannot be made easily. However, the updated information indicates a similar pattern of low concentrations of carbaryl detections in a limited number of ground water resources.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "Detections were mainly from three use sites: wheat (5.8 % of well samples from wheat land use), orchards and vineyards (1.7 % of well samples from orchard and vineyard land use), and urban (1.8% of urban groundwater samples). Data on pesticides in groundwater were reviewed by Kolpin et al. (1998) and updated information is available at: http://water.wr.usgs.gov/pnsp/pestgw/."

Page: 34 Paragraph: 3 Line: 6

EPA comment:

Limitations in analytical methodology (described elsewhere) apply to groundwater sample analysis also suggesting that there (sic) actual maximum concentrations and extent of contamination may be significantly higher.

Aventis' response:

This statement is misleading and should be deleted. The validation of the most widely used GC/MS method for the data contained in NAWQA show recoveries of 86 to 94% at spiking levels of 0.1 to 1.0 µg/L with an MDL of 0.003 µg/L. The HPLC method validation reported recoveries of 58 to 64% % at spiking levels of 0.1 to 1.0 µg/L with an MDL of 0.018 µg/L. Furthermore, using the GC/MS method, a mean recovery of 115% was found for field matrix

spikes of carbaryl at spiking levels of 0.1 µg/L. With the GC/MS method MDL of 0.003 µg/L and a mean recovery of 115% for the field matrix spikes, this method cannot reasonably be characterized as stated by EPA. Additional details of the method validations and field matrix spikes are provided in the 'Discussion Section' at the end of this response.

***EFED Response**:*

EFED has revised the text to read "Because of limitation in the analytical methods used there is some uncertainty in the quantitative accuracy of carbaryl analysis."

Page: 34 Paragraph: 3 Line: last

EPA comment:

…and updated information is available at: .

Aventis' response:

This web page was last updated in 1998. A more recent update by Kolpin was posted June 11, 2001 at:
http://water.wr.usgs.gov/pnsp/pestgw/ and is the source of the updated information included in the 'Discussion Section' at the end of this response.

***EFED Response**:*

EFED concurs with the registrant's comment and the website has been updated to read " http://water.wr.usgs.gov/pnsp/pestgw/".

Surface Water Resources

Monitoring Data

Page: 34 Paragraph: 4 Line:5-6

EPA comment:

Because of limitation in the analytical methods used there is some question as to the accuracy of carbaryl analysis.

Aventis' response:

This generalized statement needs to be qualified or deleted. Whereas the authors of reports written as part of the NAWQA program have been clear about the potential limitations of the quantitative nature of the carbaryl data in the database, they have also been clear about the validity of the qualitative nature of the data. The use of the multi-residue method in the NAWQA program does have some limitations as a result of the large numbers of diverse pesticides and degradation products that they are monitoring. However, the QC/QA data generated as part of the NAWQA program (described in the discussion section on surface

water at the end of this response) demonstrate the validity of the detections of carbaryl in the studies. The monitoring study conducted by the registrant, and reported in this section, does not have the same potential limitations in the analytical method since the method is looking specifically for carbaryl. Therefore, the analytical method used by the registrant does not raise questions about the accuracy of the carbaryl analysis.

***EFED Response**:*

EFED concurs with the registrant's comment and the text has been revised to read "Because of limitations in the analytical methods used there is some uncertainty in the quantitative accuracy of carbaryl analysis."

Page: 34 Paragraph: 4 Line:5-6

EPA comment:

Poor analytical methods probably have resulted in lower detection rates and lower concentrations than actually present.

Aventis' response:

This generalized statement should be deleted for reasons provided above and in the discussion section.

NAQWA (sic)

***EFED Response**:*

EFED concurs with the registrant's comments and the sentence has been deleted. Additionally, all references to the National Water Quality Assessment (NAWQA) acronym have been corrected.

Page: 34 - 35 Paragraph: 5 Lines: 5-8

EPA comment:

Carbaryl analytical results are fairly poor, with a typical mean percent recovery of 24% (σ = 15) in laboratory quality control samples, and a method detection limit (MDL) of 0.003 ug/L. This suggests that the values reported do not represent the maximum concentrations that exist, and that surface water contamination may be more widespread than the data show.

Aventis' response:

These statements are misleading and should be updated with further quality control data supplied by NAWQA.

A discussion of the analytical method used in the NAWQA program is presented in the USGS Open-File Report 95-181 (see Zaugg *et al*. (1995) in references). The mean percent recovery of 24% noted above can be found in Table 9 of this report and is by no means "typical". A mean recovery value of 24% was reported for reagent-grade water fortified at a level of 0.03µg/L with a method detection limit said to be 0.003 µg/L. Additional recoveries for fortified water samples (reagent-grade, ground and surface waters) ranged from 10 to 202% (see discussion section). The carbaryl data in thenot because the carbaryl concentrations are underestimated.

Additional evaluations of field blank, field matrix spike and lab control spike samples as part of the NAWQA program can be found in a provisional report by Martin (1999). This report demonstrates the lack of detection of carbaryl in 100% of the field blanks, and median recoveries of 94.4% in 306 field matrix spikes and 93.0% in 1000 lab control spikes, each at spiking levels of 0.1 µg/L. These data suggest an adequate level of detection of carbaryl in the method used in the NAWQA survey of surface and ground water. See the additional discussion at the end of this document for further information regarding recoveries in spiked surface and ground water.

EFED Response:

EFED has revised the text to read "Carbaryl is the second most widely detected insecticide after diazinon in the USGS NAWQA program (http://water.usgs.gov/nawqa/nawqa_home.html). Carbaryl was detected in 46% of 36 NAWQA study units between 1991 and 1998. The reported concentrations are believed to be reliable detections but have greater than average uncertainty in quantification. The data in the NAWQA database are amended with an "E" qualifier to indicate the variability found in the analysis. This suggests that the reported values may not represent the maximum concentrations that exist.

Page: 35 Paragraph: 2 Line: 7

EPA comment:

…at about 0.1 percent of the amount used in the basins (Larson *et al.*, 1999) . The estimated carbaryl use on in agricultural applications is about 4 million pounds suggesting that 400,000 pounds are delivered to the nations streams draining agricultural areas.

Aventis' response:

This estimated use of carbaryl for agricultural applications over-estimates the use of carbaryl by about 1 million pounds. BEAD and USGS data cited on pages 6 and 7 are consistent with lower total pounds of carbaryl applied. In addition, 0.1 percent of 4 million pounds would be **4,000** pounds, not 400,000 pounds. If the 1987 – 1996 average of 2.5 million pounds carbaryl is used in the calculation, the total load suggested to be delivered to streams draining agricultural areas would be 2,500 pounds.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "A significant portion of the total carbaryl applied was transported to streams. In areas with high agricultural use the load measured in surface waters was relatively consistent across the country at about 0.1 percent of the amount used in the basins (Larson et al., 1999) http://water.wr.usgs.gov/pnsp/rep/wrir984222/load.html. The estimated carbaryl use on in agricultural applications is about 2.5 million pounds suggesting that 2,500 pounds are delivered to the nations streams draining agricultural areas.

Registrant Monitoring Study

Page: 35 Paragraph: 4 Line: 11

EPA comment:

Carbaryl was analyzed by HPLC/MS with a limit of detection…

Aventis' response:

The analytical method used by the registrant in the surface water monitoring study uses tandem mass spectrometry (MS/MS) as the detection method. This type of detection involves quantification of "daughter" ions from a selected mass fragment and is more selective than an MS method. Therefore, to accurately reflect these differences, the method should be labeled as **HPLC/MS/MS**.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "Carbaryl was analyzed by HPLC/MS/MS with a limit of detection of 0.002 ppb (2 ppt) and a limit of quantitation (LOQ) of 0.030 ppb (30 ppt)."

Page: 36 Paragraph: 3 Line: 9

EPA comment:

In several cases finished water had higher concentration than raw water, and finished water had detectable carbaryl when the raw did not. The highest concentration measured was in finished water (0.18 ppb). Raw water sampled at the same time had much lower concentration (0.010).

Aventis' response:

This statement is misleading and certainly does not consider the analytical uncertainty for concentrations below the level of quantification and near the level of detection. There were only two cases when finished water was greater than raw water when the concentrations in finished water were greater than 0.01 ppb (only one-third of the quantification limit). One case was when the raw water was 0.009 ppb and the finished water was 0.011 ppb. These two analyses are essentially equivalent, especially considering that they are only about a third of the quantification limit. The other case was at the Deerfield community water system. This drinking water facility uses a small river without a reservoir as a source for a small Community Water System. Farms are located immediately upstream of the facility. The intake is also not continuous (shut down over weekends). Therefore, getting a matching sample is quite difficult, especially for a short duration spike as a result of spray drift, summer thunderstorm, or perhaps a spill that almost immediately enters the river a runoff event. The rarity of this event is demonstrated by the absence of residues of this magnitude the next year (2000). Samples collected through this time of the year in 2001 also do not indicate a similar event. Although the data from this site cannot be used to determine the peak concentration, the data provide a distribution of residues through the three year period which will define up to the 99th percentile concentration of the distribution.

The Deerfield, Michigan community water system is one of the systems in which the greatest variability of residues would be expected. Most of the other community water systems are located on larger rivers, lakes, or reservoirs.

Because the design of study called for analysis of finished water only when there were residues in the raw water, there was only one finished sample analyzed when the raw water contained no residues. This sample was collected at the Deerfield community water system at the sampling interval after the finding of 0.16 ppb in the Deerfield system. The residue level in this sample was 0.004 ppb. The difference between 0.004 ppb and non-detect is insignificant, and if real can probably be attributed to water at much higher concentrations remaining in the system from the previous week.

EFED Response:

The registrant's comments point out a major flaw in the water monitoring study design. The study should have analyzed finished water at all sampling times. Because of this and other shortcomings discussed previously, the results of this study cannot be used to evaluate the effects of treatment on carbaryl.

Page: 36 Paragraph: 4 Line: 1

EPA comment:

Non-targeted monitoring, such as the NAWQA program, has shown much higher concentrations occur indicating that this study, while useful, can not be used to describe the overall distributions that occur throughout the entire use area.

Aventis' response:

The targets of the drinking water monitoring conducted by the registrant and the NAWQA program are different. The NAWQA program characterized surface water concentrations within a study area while the Aventis drinking water monitoring measured residues in inlets and outlets of drinking water facilities. Also the drinking water monitoring program considered only use areas with drinking water supplies. However, for FQPA dietary assessments, the appropriate target is drinking water rather than surface water.

The main reason why the drinking water monitoring study did not show residues as high as in the NAWQA program is the location of the sampling points. Drinking water supplies tend to be located on larger surface water bodies than NAWQA sampling points (or in other words, the intakes for community water systems tend to be downstream of NAWQA sampling points). This additional time allows for additional degradation and dilution to occur. Finding the highest concentration at the Deerfield, Michigan system is not surprising since this intake is on one of the smallest surface water bodies included in the monitoring study (see response to Page: 36, Paragraph: 3, Line: 9 above for a more detailed explanation).

***EFED Response**:*

The registrant's comments express their perspective on non-targeted monitoring studies and do not reflect an error in the risk assessment.

Page: 36 Paragraph: 4 Line: 4

EPA comment:

This study does not provide sufficient information to allow estimation of actual peak and mean concentrations that actually occur in all use areas.

Aventis' response:

Because most of the samples did not contain carbaryl residues, accurate estimates of the actual peak and mean concentrations can not be obtained. However, the distributions obtained from all sites can be used to define up to the 99th percentile concentration. The average cannot be accurately determined; however, the time-weighted average is only slightly above the limit of detection (and certainly less than 0.01 ppb) at all 20 sites.

The peak concentration in this study was measured at a community water system on a small river. The registrant agrees that the sampling schedule was not adequate to determine the true peak in such systems. Most of the other community water systems are located on larger rivers, lakes, or reservoirs. Therefore, the peak values are not likely to be an order of magnitude greater than the amounts present in the collected samples.

The distributions obtained in this study are suitable for use in dietary exposure assessments. When EPA policy establishes what percentile concentration is an appropriate regulatory endpoint, then these percentiles can be determined for each of the community water systems monitoring. These percentiles can then be compared with DWLOC values in screening assessments.

***EFED Response**:*

EFED has responded previously to the utility of Aventis' water monitoring study.

Page: 37 Paragraph: 2 Line: 1

EPA comment:

Only limited information was submitted on sampling site selection…

Aventis' response:

The summary in Appendix I of this response provides a description of the sites considered for the monitoring study and the rationale for the selection of the twenty sites. This information demonstrates that the community water systems selected for this study are representative of the systems that are most likely to contain the highest concentrations of carbaryl residues.

***EFED Response**:*

EFED will review new submissions and data when available. This does not represent an error in the EFED document and so will not be addresses here. It will be addressed in an appropriate review document when it has been completed.

Page: 37 Paragraph: 3 Line: 3

EPA comment:

This should include an explanation of why this study did not observe concentrations as high as those found in other, non-targeted studies, and how the results of this study can be related to concentrations that occur throughout the country.

Aventis' response:

The main reason why the drinking water monitoring study did not show residues as high as in the NAWQA program is the location of the sampling points. Drinking water supplies tend to be located on larger surface water bodies than NAWQA sampling points (or in other words, the intakes for community water systems tend to be downstream of NAWQA sampling points). This additional time allows for additional degradation and dilution to occur. Finding the highest concentration at the Deerfield, Michigan system is not surprising since this intake is on one of the smallest surface water bodies included in the monitoring study (see response to Page: 36, Paragraph: 3, Line: 9 above).

Since the drinking water study targeted drinking water systems in high-use watersheds, the data from this study are representative of the drinking water systems most likely to contain carbaryl.

***EFED Response**:*

EFED has already commented on the utility of Aventis' water-monitoring study. Please refer to the previous discussions.

Sacramento-San Joaquin River Delta

Page: 37 Paragraph: 4 Line: 4 - 5

EPA comment:

Carbaryl was found to be the sole causative agent at one of 20 sites…
The toxicity seemed to persist for several days…

Aventis' response:

The statement should be revised. The reference cited (Werner *et al*., 2000) lists carbaryl as "the primary toxicant" (not as the "sole causative agent"), even though an unknown was also found at the same time. No information about the "unknown" is provided. Both conclusions of "sole causative" and of "primary toxicant" cannot be substantiated without further evidence about the nature and concentration of the unknown. Actually, for another site the authors concluded about the unknown found there "*in 3 of 21 samples, toxicity observed could not be entirely explained by the identified primary toxicants.*" Additionally, it is at least questionable if the analytical method employed would detect all potential toxicants beside the insecticides it was set up for.

The toxicity seeming to persist is not explained or substantiated in the reference. The citation of such dubious results should be removed from the RED.

***EFED Response**:*

EFED has revised the text; it now reads "Carbaryl was found to be the [primary] toxicant at one of 20 sites sampled in 1995, with concentration of 7.0 µg/L." Furthermore, the reference cited (Werner, et al. 2000) is taken from a peer-reviewed journal, i.e., Environmental Toxicology and Chemistry, which EFED does not consider to be a dubious source.

6.0 Hazard and Risk Assessment for Aquatic Organisms

Hazard assessment for Aquatic organisms

Estuarine/Marine Fish

Page: 39 Paragraph: 2 Line: 6

EPA comment:

…carbaryl water concentration of 1.2 µg/ml…

Aventis' response:

To be consistent with the rest of the document the units should be presented in ppm ("carbaryl water concentration of 1.2 ppm")

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised to read "1.2 ppb".

Aquatic Plants

Page: 40 Paragraph: 2 Line: 6

EPA comment:

Guideline 122-2 is not fulfilled.

Aventis' response:

The chapter should be revised. As detailed above (comments to Page 2 of the Memorandum), studies were submitted in 1992. The status for this requirement in an October 04, 2000 OPP Guideline Status Report (Chemical Review Management System) lists the guideline 122-2 status as "Acceptable/Satisfied".

***EFED Response**:*

As EFED has noted previously in its response to comments, EPA requires data on 5 aquatic plant species. The registrant has provided data on only two of the five species that were classified as acceptable and as having fulfilled guideline test requirements. Therefore, EFED is requesting that aquatic plant studies be repeated following EPA guidelines.

Risk Assessment for Aquatic Organisms

Page: 40 Paragraph: 4 Line: 3

EPA comment:

…corresponding levels of concern (LOCs) is presented in Appendix D.

Aventis' response:

The risk quotients are currently listed in Appendix C.

***EFED Response**:*

EFED concurs with the registrant's comments and the text has been revised; the sentence now reads "A detailed analyses of risk quotients (RQs) in relation to their corresponding levels of concern (LOCs) is presented in Appendix C."

Estuarine/Marine Fish

Page: 42 Paragraph: 1 Line: 17/18

EPA comment:

Chronic toxicity studies with an estuarine/marine fish species is required.

Aventis' response:

This requirement should be waived. Given the relatively short half-life of carbaryl in the aquatic environment and the low acute risk, it is unlikely that estuarine/marine fish species would be exposed to a chronic risk.

EFED Response:

This is not an error and is more appropriately addressed in a later phase of the reregistration process.

Page: 42 Paragraph: 2 Line: 1

EPA comment:

There is one carbaryl use in particular that presents a major acute and chronic risk to estuarine/marine fish.

Aventis' response:

This sentence should be rephrased. While there might be an acute risk from the application to oyster beds, given that there is only one application every six years according to the reference cited by EPA, it is improbable that estuarine/marine fish would be exposed to a chronic risk.

EFED Response:

In a study by Stonic (1999) application of carbaryl to mud flats in Willapa Bay, Washington, resulted in post-spray carbaryl concentrations at sprayed sites ranging from 2,000 to 3,400 ppb by 2 days after treatment (DAT), 180 to 220 ppb by 30 DAT, and 86 - 120 ppb by 60 DAT. These data suggest that the potential for chronic exposure to estuarine/marine fish is possible. However, EFED has rephrased the sentence to read "There is one carbaryl use in particular that represents a potential acute and chronic risk to estuarine/marine fish." The full reference for these data is: Stonic, Cynthia. 1999. Screening Survey of Carbaryl (Sevin™) and 1-naphthol Concentrations in Willapa Bay Sediments. Washington State Department of Ecology. Publication No. 99-323.

7.0 Hazard and Risk Assessment for Terrestrial Organisms

Hazard Assessment for Terrestrial Organisms

Mammalian

Page: 46 Paragraph: 4 Line: 1

EPA comment:

With a rat LD_{50} of 307 mg/kg…

Aventis' response:

Typographical error, the rat LD_{50} is 301 mg/kg.

EFED Response:

EFED concurs with the registrant's comments and has corrected the text to indicate a rat LD_{50} of 301 mg/kg.

Risk Assessment for Terrestrial Organisms

Avian Risk

Nongranular Formulations

Page: 47 Paragraph: 4 Line: 5

EPA comment:

…levels of concern (LOCs) is presented in Appendix D.

Aventis' response:

The risk quotients are currently listed in Appendix C.

EFED Response:

EFED concurs with the registrant's comments and has revised the text to reflect that risk quotients and their associated levels of concern (LOCs) are presented in Appendix C.

Page: 48 Paragraph: 1 Line: 3

EPA comment:

… for 34 of 43 uses at maximum reported rates, and for 37 of 72 uses at "average" rates. (Appendix D, …

Aventis' response:

The risk quotients are currently listed in Appendix C.

***EFED Response**:*

EFED concurs with the registrant's comments and has revised the text to reflect that risk quotients and their associated levels of concern (LOCs) are presented in Appendix C.

Granular Formulations

Page: 48 Paragraph: 2 Line: 5

EPA comment:

…for any of the granular carbaryl uses (Appendix D, Table 6).

Aventis' response:

The risk quotients are currently listed in Appendix C.

***EFED Response**:*

EFED concurs with the registrant's comments and has revised the text to reflect that risk quotients and their associated levels of concern (LOCs) are presented in Appendix C.

Mammalian Risk

Risk to Herbivores/Insectivores: Nongranular Formulations

Risk Quotients for Herbivores/Insectivores Based on Less than Maximum Label Use Rates

Page: 48 Paragraph: 3 Line: 3 & 4

EPA comment:

… (Appendix D, Table 10a) and maximum reported (Doane data) use rates data available for 43 uses (Appendix D, Table 10b)

Aventis' response:

The risk quotients are currently listed in Appendix C.

***EFED Response**:*

EFED concurs with the registrant's comments and has revised the text to reflect that risk quotients and their associated levels of concern (LOCs) are presented in Appendix C.

Risk Quotients for Herbivores/Insectivores Based on Maximum Label Use Rates

Page: 48 Paragraph: 6 Line: 1

EPA comment:

Carbaryl is moderately toxic to small mammals on an acute oral basis (rat LD_{50} = 307 mg/kg)

Aventis' response:

Typographical error, the rat LD_{50} is 301 mg/kg.
By using the lower LD_{50} all acute mammalian risk quotients will change slightly.

EFED Response:

EFED concurs with the registrant's comments and has corrected the text to indicate a rat LD_{50} of 301 mg/kg. The mammalian risk quotient tables in Appendix C and the ranges reported in the text have been revised to reflect the modest change in numbers.

Page: 49 Paragraph: 1 Line: 3

EPA comment:

…corresponding levels of concern (LOCs) is presented in Appendix D.

Aventis' response:

The risk quotients are currently listed in Appendix C.

EFED Response:

EFED concurs with the registrant's comments. The sentence has been revised to read "A detailed analysis of mammalian RQs in relation to their corresponding levels of concern (LOCs) is presented in Appendix C."

Risk to Granivores: Nongranular Uses

Chronic risk: Nongranular Uses

Page: 50 Paragraph: 2 Line: 8

EPA comment:

…summarized in Appendix D, Table 9.

Aventis' response:

The risk quotients are currently listed in Appendix C.

***EFED Response**:*

EFED concurs with the registrant's comments and has revised the text to reflect that risk quotients and their associated levels of concern (LOCs) are presented in Appendix C.

Reproduction Effects

Page: 50 & 51 Paragraph: 4 / 1

EPA comment:

(Review of alleged reproduction effects of carbaryl).

Aventis' response:

The paragraphs should be changed. The literature cited in these paragraphs show ambivalent results. While some references seem to support the claim of reproductive effects, other references do not. The potential for reproductive effects in mammals was evaluated in the recently submitted 2-generation study in rats. No reproductive effects were seen in this guideline study. The NOAEC of 75 ppm was based on pup mortality.

***EFED Response**:*

EFED believes that the chronic effects cited from the open literature are legitimate. As stated previously, chronic reproductive tests have resulted in effects that support EFED's concerns regarding the endocrine disrupting potential of carbaryl. EFED believes that the chronic effects cited from rat developmental studies, i.e., reduced reproduction, disturbances in spermatogenesis, increased resorption of embryos, increased incidence of infertility in females and underdeveloped testes in males, also represent serious reproductive effects that support EFED's concerns regarding the chronic reproductive/developmental toxicity of carbaryl. Just because one study failed to show similar effects to another, EFED does not believe that it would be reasonable to discount the validity of the earlier studies. If anything, the data strongly suggests that additional data are needed to better understand the likelihood of adverse effects.

Page: 51 Paragraph: 4

EPA comment:

Feeding 2 or 20 mg/kg of carbaryl to pregnant rhesus monkeys (*Macacca mulatta*)

Aventis' response:

This paragraph should be deleted. As there are no native monkey species in the U.S., this reference is irrelevant for U.S. wildlife species. Additionally, the reference cited is only a brief abstract article consisting of one 17-line paragraph. Such information should not be the basis for use in a RED risk assessment.

***EFED Response**:*

The basis for the EFED risk assessment is the mammalian acute (LD50 = 301 mg/kg) and chronic (NOAEC = 80 ppm) rat toxicity data. The data from rhesus monkeys are used to further characterize risk. While the registrant is correct that rhesus monkeys are not native to the United States, these animals are routinely used in primate research and are considered reasonable surrogates for studying the effects of chemicals on humans.

9.0 References (non-MRID)

Some of the references cited in EPA's list are not full scientific articles, but only abstracts from meetings (e.g. DeNorsica, 1973; Doughtery et al. , 1971, Chapin et al. 1997). Such "publications" should not be used as references considered in risk assessments. Without a sufficient description of methods and a presentation of detailed results these studies cannot be evaluated to determine if the findings are or are not scientifically plausible. Similarly, at least three of the references (Gladenko *et al.* 1970, Krylova *et al.* 1975, Smirnov *et al.* 1971) cited as proof for reproductive toxicity are in Russian in Cyrillic writing making an appropriate and timely evaluation difficult. Due to the limited review time during the 30-day comment period, the registrant could not peruse all references. A more detailed response will be provided during the 60-day comment period.

***EFED Response**:*

EFED has cited literature from peer-reviewed journals and considers these sources to be reliable. Furthermore, the registrant is providing their perspective on open literature and is not citing a specific error in the risk assessment.

Page: 59

EPA comment:

Carmel, R.F., Imhoff, J.C., Hummel, P.R., Cheplick, J.M. and Donigan, A.S., 1997.

Aventis' response:

The first name should be Car**s**el.

***EFED Response**:*

EFED concurs with the registrant's comment and has corrected the reference to reflect the correct spelling of the name "Carsel".

Page: 59

EPA comment:

Nkedi-Kizza and Brown (1988)

Aventis' response:

The date should be 19**9**8.

EFED Response:

EFED concurs with the registrant's comment and has corrected the reference to reflect the correct date of publication, i.e., 1998.

Appendix A: Environmental Fate Study Reviews (DERs)

Page: 62 ff

EPA comment:

(Environmental fate DERs are included)

Aventis' response:

The DERs should not be included in the RED. Publication of DERs together with the RED is unusual and will put Aventis in a competitive disadvantage.

EFED Response:

EFED concurs with the registrant's comments that DERs should be made available to the public under the Freedom of Information Act after they have been reviewed and cleared for confidential business information. EFED also wants to reduce the overall size and level of detail of its risk assessment for readability. EFED does not, however, take a position regarding Aventis' statement on "a competitive disadvantage" resulting from DER publication.

Appendix B: Refined Water Memo

Aventis' response:

This memo was provided as an electronic copy and needs to be inserted into the document. It included text that repeated several sections of the EFED document and it included PRZM input tables for the drinking water concentrations using the Index Reservoir scenario. It would have been of benefit to have the same PRZM inputs for the "standard pond" scenarios that were used to estimate surface water concentrations used in the aquatic risk assessments.

***EFED Response**:*

The full text of the Refined Water Memo has been included in Appendix B of the EFED chapter. The memo includes both PRZM input and output files.

Appendix C: Ecological Risk Assessment

Toxicity Endpoints Used in the Risk Assessment

Page: 129 (e-version)

EPA comment:		**Aventis' response**:
Mammalian acute oral LD50	rat = 307 mg/kg	The correct LD_{50} is 301 mg/kg
Mammalian chronic (reproduction) NOAEC	rat = 80 ppm	The result of the recently submitted 2-generation rat study should be used (75 ppm)

***EFED Response**:*

As indicated previously, EFED has corrected the typographical error regarding the mammalian acute oral LD_{50} of 301 mg/kg. Additionally, EFED has already commented regarding the recently submitted 2-generation rat study; even if the study is classified as acceptable, the change in NOAEC from 80 ppm to 75 ppm will not significantly affect the magnitude of the risk quotients. Neither of these changes have a marked impact on EFED's risk assessment.

Avian Acute and Chronic Risk

Page: 130 (e-version) Paragraph: 1 Line: 1

EPA comment:

Since the avian LC_{50} is greater than 5,000 ppm (Appendix E),

Aventis' response:

The toxicity data are currently listed in Appendix D.

EFED Response:

EFED concurs with the registrant's comments and the text has been revised to read that toxicity data are listed in Appendix D.

Page: 132 – 135 (e-version)

EPA comment:

(Acute Risk Quotients in Tables 4 and 5, as well as throughout the document were a reference is made to these quotients)

Aventis' response:

As the acute risk quotients are calculated on the basis of an LC_{50} of > 5000 ppm, the quotients should be given as "< (value)", not just the value. The values should also be changed accordingly throughout the document where a reference is made to these quotients.

EFED Response:

EFED concurs with the registrant's comments and Appendix C Tables 4 and 5 have been revised to show that acute risk quotients are less than the values presented. No further changes were necessary in the text since acute avian risk quotients were reported as being less than levels of concern.

Risk from Exposure to Non-granular Products

Page: 137 – 147 (e-version)

EPA comment:

(Text and tables 7 - 10)

Aventis' response:

Text and tables should be revised. A rat LD_{50} of 307 mg/kg was used to calculate the acute risk quotients. The correct value is 301 mg/kg.

For calculation of the chronic risk quotient a NOAEC of 80 ppm was taken from a developmental study. The NOAEC of 75 ppm from a more relevant 2-generation rat study recently submitted should be used instead.

EFED Response:

As noted previously, the mammalian acute LD_{50} value has been corrected to 301 mg/kg and the acute risk quotients have been revised. Additionally, the chronic risk quotients are still based on

a NOAEC of 80 ppm. The data from the 2-generation rat study have not been reviewed; however, the change in NOAEC from 80 to 75 ppm will have no marked effect in EFED's risk assessment.

Risk from Exposure to Granular Products

Page: 147 & 148 (e-version)

EPA comment:

(Text and Table 11)

Aventis' response:

Text and tables should be revised. A rat LD_{50} of 307 mg/kg was used to calculate the acute risk quotients. The correct value is 301 mg/kg.

EFED Response:

As noted previously, references to the rat LD_{50} have been corrected to represent a value of 301 mg/kg. Table 11 has been corrected.

Aquatic Plants

Page: 152 (e-version)

EPA comment:

Based on a single core aquatic plant toxicity study available…
…recommended that toxicity studies with *Lemna gibba, Anabaena flos-aquae, Skeletonema costatum,* and a freshwater diatom be submitted.

Aventis' response:

The respective studies were submitted to the Agency in 1992 (see comments above to Page 2 of the Memorandum for a complete list and status).

EFED Response:

As noted previously, EPA requires data on 5 aquatic plant species. Only two of the five species provided data that were classified as acceptable and as having fulfilled guideline test requirements. Therefore, EFED is requesting that aquatic plant studies are repeated following EPA guidelines.

Appendix D: Toxicity Assessment

Page: 157 (e-version)

EPA comment:

Table 1 (spelling of author in MRID No. 00160000)

Aventis' response:

The author of MRID No. 00160000 should be "Hudson *et al.* ".
Also, it is not obvious why the same reference is one time classified "core" and six times "supplemental". The agency should reconsider if the use of a "supplemental" study (i.e., rock dove) in calculating all acute RQ values is justified.

EFED Response:

Table 1 has been revised to contain the correct spelling of the reference "Hudson et al." Study classifications reported in Table 1 are based on whether recommended species were used for testing. The only study reported in Table to use the recommended species, i.e., mallard ducks, is classified as core; the remaining studies did not use recommended species and thus are classified as supplemental.

Birds, Chronic Toxicity

Page: 158 (e-version) Paragraph: 3

EPA comment:

Bird kills attributed to carbaryl and involving blackbirds, ducks, starlings, grackles turkey, and cardinals have been reported in Pennsylvania, Virginia, New Jersey, North Carolina and Michigan (#1002048-001, #1000802-001, #1007720-020, ##1000799-003, #1004375-004).

Aventis' response:

The paragraph should be moved to the acute bird section.
Also, only individuals familiar with this information will recognize the numbers as the incident numbers from the EIIS database. An appropriate reference should be inserted here and in similar citations.

EFED Response:

EFED concurs with the registrant's comments and the paragraph has been moved to the discussion on acute avian toxicity. Additionally, a reference has been inserted into the paragraph indicating that the information was based on 6(a)2 ecological incident data.

Page: 158 Paragraph: 1 Line: 2 & 3

EPA comment:

Exposure to carbaryl at levels equal to or greater than 1000 ppm in the mallard duck results in adverse reproduction effects, such as decrease in number of eggs produced include cracked eggs, fertility, embryonic mortality, and hatching success.

Aventis' response:

The sentence should be changed. The embryonic mortality and the hatching success were not different from the control.

EFED Response:

As stated previously, although the data evaluation record for the avian reproduction study lists increased embryonic mortality and reduced hatching success as significant effects, reference to these two effects has been deleted from the text since the original study by Fletcher was not available for secondary review. However, reduced egg production, increased incidence of cracked eggs and decreased fertility are reproductive effects that support EFED's concerns regarding the endocrine disrupting potential of carbaryl.

Mammals, Acute and Chronic

Page: 158 & 159 (e-version)

EPA comment:

(rat LD_{50} of 307 mg/kg, NOAEC 80 ppm)

Aventis' response:

The acute LD_{50} value for rat should be corrected to 301 mg/kg, and the chronic NOEAC to 75 ppm from the 2-generation rat study.

EFED Response:

As noted previously, the mammalian acute LD_{50} value has been corrected to 301 mg/kg and the acute risk quotients have been revised. Additionally, the chronic risk quotients are still based on a NOAEC of 80 ppm. Data from the 2-generation rat study have not been reviewed; however, the change in NOAEC from 80 to 75 ppm will have no marked effect in EFED's risk assessment.

Freshwater Fish, Acute

Page: 161 (e-version)
EPA comment:
Table 6

Aventis' response:
The study classification of reference MRID 40098001 (Mayer & Ellersieck, 1986) should be reconsidered (and handled in a consistent fashion). A number of times the reference is classified "core", while in other instances the classification is "supplemental". The reference is an overview article with little description of test methods, analytical procedures, GLP, or study details. The results are generally listed in extensive tables (although summarized in the text for some chemicals). Such a review article cannot be regarded as a "core" study equivalent to the guideline studies that have to be prepared by registrants. Also, such studies with insufficient test method descriptions should not be used in a risk assessment as the primary source of information. A submission based on such data would have certainly been rejected by the Agency

EFED Response:

The classification of Mayer and Ellerieck (1986) data reported in Table 6 as either core or supplemental depends on whether EPA-recommended species were used for testing. Unlike avian toxicity studies where only a limited number of species are recommended for testing, there is a broad range of fish species that EPA views as acceptable for testing. In Table 6, chinook salmon were the only species not recommended by EPA for testing; therefore, the data based on Chinook salmon were classified as supplemental.

The only acceptable data available on technical grade carbaryl other than a study on largemouth bass by Johnson and Finley (1980) were from Mayer and Ellersieck (1986). The registrant is encouraged to submit data on the acute toxicity of technical grade carbaryl to address the uncertainties that they have identified.

Freshwater Invertebrates, Acute

Page: 163 (e-version)
EPA comment:
Table 9

Aventis' response:
The study classification of reference MRID 40098001 (Mayer & Ellersieck, 1986) should be reconsidered (and handled in a consistent fashion). A number of times the reference is classified "core", while in other instances the classification is "supplemental". The reference is a review article with little description of test methods, analytical procedures, GLP, or

study details. The results are generally listed in extensive tables (although summarized in the text for some chemicals). Such an overview article cannot be regarded as a "core" study equivalent to the guideline studies that have to be prepared by registrants. Also, such studies with insufficient test method descriptions should not be used in a risk assessment as the primary source of information.

EFED Response:

The classification of Mayer and Ellerieck (1986) data reported in Table 6 as either core or supplemental depends on whether EPA-recommended species were used for testing. As with the freshwater fish studies discussed previously, the registrant is encouraged to submit data on the acute toxicity of technical grade carbaryl to address the uncertainties that they have identified.

Estuarine and Marine Invertebrates, Acute

Page: 165 (e-version)

EPA comment:

Table 13, reference for glass shrimp: Mayer & Ellerersieck

Aventis' response:

The reference should be corrected in Mayer & Ellersieck.

EFED Response:

EFED concurs with the registrant's comments and the reference in Table 13 has been corrected to read "Mayer & Ellersieck (1986)."

Page: 167 (e-version) Table 15

EPA comment:

Table 15, reference for MRID No. 00265665

Aventis' response:

The reference for MRID No. 00265665 should also contain the citation of an author.

EFED Response:

The reference to MRID 00265665 (Eastern oyster LC_{50} = 2.5 ppm) has been deleted from Table 15.

DISCUSSION

EFED Response:

EFED has already responded to all of the issues discussed in this section. The reader is referred to earlier responses to comments.

1. Surface Water Concentrations

Summary of Registrant Surface Water/Drinking Water Monitoring Program

In section V, page 31 EPA states that the modeling simulations provide a conservative, though not unreasonable, estimate on possible concentrations in drinking water. The data from the registrant drinking water monitoring program provide the best estimate of concentrations of carbaryl in drinking water. This study uses the sampling design for acute endpoints recommended in industry/EPA meetings during 1999 (weekly sampling during times of peak concentrations over a three year period). Twenty sites representing the highest carbaryl use areas were selected based on the information provided in Appendix I. These included 16 sites in agricultural areas and 4 locations in urban areas. Samples were collected from the inlet and outlet water at each sampling interval. Outlet samples were only analyzed when residues were present in the inlet samples. The analytical method had a limit of quantification of 0.030 ppb and a limit of detection of 0.002 ppb.

Table 1 summarizes the results of the monitoring at each of the 20 community water systems. The maximum concentration observed was 0.16 ppb (average of four samples, the highest was 0.18 ppb) in a finished water sample from the Deerfield community water system located on the River Raisin in Lenawee County, Michigan. There were only five other samples above the limit of quantification of 0.030 ppb. One was a raw water sample containing 0.31 ppb from the Little Potato Slough Mutual community water system near Lodi in San Joaquin County, California (the source is the Little Potato Slough). The corresponding finished water sample was 0.007 ppb. A second one was a raw water sample in Brockton, MA, which contained 0.031 ppb. No detectable residues were found in the corresponding finish water sample. The last three samples were from the Shades Mountain plant of the Birmingham community water system on the Cahaba River in Jefferson County, Alabama. Two were raw and finished samples of 0.038 and 0.032 ppb at the same sampling interval in 2001. The other sample was 0.035 ppb in the raw water in a 2000 sample (the corresponding finished sample did not contain carbaryl residues. All residues were transient so the time-weighted average concentration of carbaryl in each of the years was 0.005 ppb or less at all 20 community water systems.

Table 1. Summary of Results from the Carbaryl Drinking Water Monitoring Study.

Site	Major Uses	Maximum Concentration (ppt)						TWA Conc. (ppt)* in Outlet Water	
		Inlet Water			Outlet Water				
		1999	2000	2001**	1999	2000	2001**	1999	2000
Manatee, FL	citrus	9	3	ND	11	ND	NA	1	1
West Sacramento,	orchards,	3	24	ND	3	10	NA	1	1
Lodi, CA	orchards,	12	31	ND	4	7	NA	1	1
Riverside, CA	grapes, tree	8	ND	ND	ND	NA	NA	1	1
Lake Elsinore,	citrus	ND	3	6	NA	NA	Analysis	1	1
Corona, CA	citrus	ND	ND	ND	NA	NA	NA	1	1
Beaumont, TX	various	ND	ND	ND	NA	NA	NA	1	1
Point Comfort,	rice, tree	18	5	ND	ND	ND	NA	1	1
Penn Yan, NY	grapes,	ND	23	ND	NA	ND	NA	1	1
Westfield, NY	grapes,	21	5	ND	ND	9	NA	1	1
Jefferson, OR	vegetables,	ND	10	ND	NA	ND	NA	1	1
Coweta, OK	pecans	4	ND	***	ND	NA	***	1	1
Pasco, WA	apples,	2	3	ND	ND	ND	NA	1	1
Manson, WA	apples	ND	ND	ND	NA	NA	NA	1	1
Deerfield, MI	vegetables	10	4	ND	160	ND	NA	5	1
Brockton, MA	cranberries	31	27	ND	ND	3	NA	1	1
East Point, GA	home and	18	18	4	3	8	ND	1	1
Midlothian, TX	home and	14	ND	14	ND	NA	ND	1	1
Cary, NC	home and	4	ND	ND	ND	NA	NA	1	1
Birmingham, AL	home and	23	35	38	ND	ND	32	1	1

* Annual Time Weighted Concentration, outlet values substituted for inlet values when available; values below the detection limit were considered to be half the detection limit.
** Results represent one to six months of sampling into the third year program.
*** No results available for the third year of sampling.
ND Not detected.

NA No outlet samples analyzed due to carbaryl residues not being detected in inlet samples.

Summary of Surface Water Data from the NAWQA Program

In Section 1 page 3, Section 4 page 28 and in Section 5 page 34, EPA has summarized the available surface water monitoring data from the NAWQA program as having detections in 46% of the 36 NAWQA study units between 1991 and 1998 with a maximum concentration of 5.5 ppb. The following tables summarize the carbaryl analyses presently available from this database.

Table 2 is a summary of the carbaryl detections in the updated database analysis recently reported by Larson (2001). This analysis was conducted only for samples collected during a one-year period of the most intensive sampling from each of the sampling sites. Numerous samples were excluded from this analysis as described by Larson:

> *"A few sites with sufficient sampling for pesticides were excluded from the analysis, in order to minimize bias caused by over-representation of a particular land use or agricultural setting. ... The sampling requirements for a site to be included in the analysis were a minimum of 8 samples collected in 6 or more months during the 1-year period. In addition, samples must have been collected during the expected period of elevated pesticide concentrations. At most of the sites used in this analysis, 20 to 30 samples were collected during the selected 1-year period.... Not all samples collected during the year at each site were used in the calculation of the summary statistics, however. Samples collected as part of a fixed-frequency sampling schedule were included, along with a much smaller number of samples collected during selected high or low flow conditions. Samples collected over a storm hydrograph, or as part of a study of diurnal variability, were excluded in order to avoid bias resulting from repeated sampling during extreme conditions. "*

Table 2.Carbaryl Detections Reported in Pesticides in Streams Update (Larson, 2001)

Site Type	Number of	**Number**	**Carbaryl Detection Frequency (%)**				**Maximum**
			All	**>=0.01**	**>=0.05**	**>=0.10**	
Agricultural	62	1560	9.2	5.7	1.8	0.9	5.2
Urban Streams	22	611	43	37	19	12	3.2
Integrator[A]	31	595	15	11	2.7	1.2	0.43

[A] Large streams and rivers

Results in Table 3 and Table 4 show a breakdown of all the carbaryl analyses reported in the USGS NAWQA database, which was downloaded from their web site July 16, 2001. The data are reported separately for the GC/MS and HPLC/PDA analyses.

Table 3. Frequency of Carbaryl Detections by GC/MS in Different Concentration Ranges Reported in the NAWQA Database as of July 16, 2001

Land Use	Number	<=MDL[C]		>0.003 to		>0.01 to 0.1		>0.1 to 1 ppb		>1 ppb	
		No.	%	No.	%	No.	%	No.	%	No.	%
All Samples	10379	8388	80.82	617	5.94	1065	10.26	283	2.73	26	0.25
Agricultural	4349	3888	89.40	188	4.32	225	5.17	46	1.06	2	0.05
Urban	1763	921	52.24	161	9.13	463	26.26	195	11.06	23	1.30
Mixed[A]	3648	3022	82.84	247	6.77	345	9.46	33	0.90	1	0.03
Other[B]	619	557	89.98	21	3.39	32	5.17	9	1.45	0	0

[A] Large streams and rivers. Includes all of the "Integrator" sites listed in Larson, *et al.* ., 1999 and many more.
[B] Includes forest, rangeland, mining, etc.
[C] The method detection limit (MDL) for carbaryl analyzed by the GC/MS method is 0.003 µg/L, but updated MDLs presented in the database may be higher for some analyses and are included in this category.

Table 4. Frequency of Carbaryl Detections by LC/PDA in Different Concentration Ranges Reported in the NAWQA Database as of July 16, 2001

Land Use	Number	<=MDL[C]		>0.008 to		>0.01 to 0.1		>0.1 to 1 ppb		>1 ppb	
		No.	%	No.	%	No.	%	No.	%	No.	%
All Types	5516	5348	96.95	9	0.16	93	1.69	54	0.98	12	0.22
Agricultural	2528	2509	99.25	1	0.04	13	0.51	3	0.12	2	0.08
Urban	1189	1064	89.49	4	0.34	64	5.38	47	3.95	10	0.84
Mixed[A]	1523	1501	98.56	4	0.26	15	0.98	3	0.2	0	0
Other[B]	276	274	99.28	0	0	1	0.36	1	0.36	0	0

[A] Large streams and rivers. Includes all of the "Integrator" sites listed in Larson, *et al.* ., 1999 and many more.
[B] Includes forest, rangeland, mining, etc.
[C] The method detection limit (MDL) for carbaryl analyzed by the LC/PDA method is 0.008 µg/L, but updated MDLs presented in the database may be higher for some analyses and are included in this category.

Summary of Carbaryl Analytical Methods used in the NAWQA Program

In a number of instances throughout their review, EPA has made reference to the "poor recovery" for carbaryl noted in a NAWQA summary document (Larson, 1999). In this document, reference is made to mean percent recovery of 24% for carbaryl with a method detection limit (MDL) of 0.003 ppb. The Agency cites this low mean recovery several times as evidence that the concentrations of carbaryl reported in the database widely underestimate the actual concentrations of carbaryl in the water samples. This claim is misleading and should be removed from each location in the draft RED for reasons discussed below.

Two analytical methods were developed as part of the NAWQA program and both of them have been used in the analysis of carbaryl. The first method, used for a majority of the NAWQA data reported for carbaryl, is a GC/MS method with an MDL of 0.003 ppb (Zaugg, *et al.*, 1995). The second method, used for a limited number of samples in which carbaryl was analyzed, is an

LC/Photodiode-Array (PDA) method with an MDL of 0.008 ppb (Werner *et al.* ., 1996). In the NAWQA database the quantitative data for carbaryl determined by the GC/MS method are flagged with an "E", as are data for several other analytes, indicating that the analysts have noted "the potential for variable performance" in the analysis of carbaryl. None of the carbaryl data in the NAWQA database has been corrected for procedural recoveries that were noted in the documents described above. Both of these methods are discussed below in relation to the recoveries found for the methods and the potential impact this could have on the analytical data for carbaryl.

Gas Chromatography/Mass Spectroscopy Method

The analytical method most used in the NAWQA program for the analysis of carbaryl in water samples is the GC/MS method described by Zaugg, *et al*., 1995. In this multi-residue method, the analytes are first removed from the water sample by sorption on a C-18 solid phase and are subsequently eluted from the solid phase, separated by GC and quantified by mass spectroscopy with selected ion monitoring. The identity of each analyte is confirmed by the appropriate combination of retention time and the ratios of three mass ions that are characteristic for the analyte.

The recoveries for carbaryl spiked at different levels into three different types of water and analyzed by the GC/MS method are shown in Table 5 Mean percent recoveries of 151 and 202% were found for carbaryl fortified at 0.1 and 1.0 µg/L in reagent grade water. A preliminary MDL of 0.046 µg/L was calculated for the 0.1 µg/L spiking level. Mean percent recoveries of 10 and 75% were found for carbaryl fortified at 0.1 and 1.0 µg/L in a surface water sample collected from the South Platte River. However, carbaryl was detected at 0.18 µg/L in this water, or nearly twice the low spike level, raising questions about the validity of this result. Mean percent recoveries of 94 and 86% were found for carbaryl fortified at 0.1 and 1.0 µg/L in a ground water sample collected from a well in Denver. A mean recovery value of 24% was reported for reagent-grade water fortified at a level of 0.03 µg/L with a method detection limit calculated at 0.003 µg/L.

Table 5. Recovery and Precision for Multiple Determinations of Carbaryl in GC/MS Method for Carbaryl Spiked in Different Water Samples

Water type	Spike Concentration	Mean Recovery (%)	MDL Calculated
Reagent Grade	0.1	151	0.046
Reagent Grade	1.0	202	-
Surface[A]	0.1	10	-
Surface[A]	1.0	75	-
Ground[B]	0.1	94	-
Ground[B]	1.0	86	-
Reagent Grade	0.03	24	0.003

[A] Surface water was collected from the South Platte River near Henderson, Colorado. This water was found to contain significant concentrations of several pesticides including 0.18 µg/L carbaryl. This concentration was subtracted from the values determined to give corrected results.

[B] Ground water was collected from the Denver Federal Center Well 15.

Whereas the values reported by Zaugg, *et al*. (1995) are of interest in validating the analytical method, they are not as useful in evaluating the validity of the data contained in the NAWQA database. Therefore, quoting the mean recovery value of 24% for reagent grade water spiked with carbaryl at 0.03 µg/L as evidence that the concentrations reported in the database underestimate the actual concentrations of carbaryl present in the water samples is misleading. A more useful measure of the validity of the values in the database lies with the quality control checks that have been incorporated into the analysis of samples in the NAWQA program.

In a preliminary report, Martin (1999) reported the quality control data collected as part of the NAWQA surface and ground water programs by the 1991 NAWQA Study Unit teams or the National Water Quality Laboratory (NWQL) during 1992 to 1996. The data that were compiled includes field blanks, laboratory control spikes and field matrix spikes, which are defined below by Martin.

> *"Field blanks were collected at the field site with pesticide-grade blank water and are exposed to the field and laboratory environments and equipment similarly to environmental samples. Field blanks measure the frequency and magnitude of contamination (one type of positive bias) in environmental water samples from sources in the field and/or laboratory. Contamination is the main cause of false-positive detections (detecting a pesticide in a sample when, in truth, it is absent)."*
>
> *"Laboratory control spikes measure the bias and variability of the analytical method at a particular concentration. One laboratory control spike is measured in each analytical set of environmental samples. The laboratory control spike has the target pesticides spiked into pesticide-grade blank water at the laboratory and extracted, processed, and analyzed like environmental samples. Laboratory control spikes analyzed by GCMS were spiked at 0.1 µg/L…"*
>
> *"Field matrix spikes measure the bias and variability of the analytical method PLUS any potential effects caused by (1) degradation of pesticides during shipment to the laboratory, (2) inferences in the determination of pesticides from unusual characteristics of the environmental water sample ("matrix effects"), and (3) other chemical processes that cause bias or variability in the measurements of pesticides in environmental water samples. Field matrix spikes analyzed by GCMS were spiked at 0.1 µg/L,…"*

All of the carbaryl analyses in the field blanks, field matrix spikes and lab control spikes were conducted following the same method described by Zaugg *et al*., 1995 that was used to generate a majority of the carbaryl data contained in the NAWQA database. The data below were excerpted from Tables 1 to 4 of the Martin report. Carbaryl is found in these tables under parameter 82680.

Out of 145 samples taken as ground water field blanks, carbaryl was not detected in any of the samples indicating a lack of false positives. Out of 171 samples taken as surface water field

blanks, carbaryl was reported in two samples (1.2% false positives) at reported concentrations of 0.009 and 0.012 µg/L.

A summary of the results for the field matrix spikes and the lab control spikes is presented in Table 6 Mean recovery for the 306 field matrix spikes was 115% of the spiking level of 0.1 µg/L with a median recovery of 94.4% and a 90th percentile recovery of 200%. This indicates the potential for the method to over-estimate the concentration of carbaryl present in the water samples and is consistent with the initial data reported for the reagent water samples by Zaugg *et al*. (1995). Mean recovery for the 1000 lab control spikes was 99.6% of the spiking level of 0.1 µg/L with a median recovery of 93% and a 90th percentile recovery of 185%. These data suggest an adequate level of detection of carbaryl in QC samples that were analyzed as part of the same process used in the NAWQA survey of pesticides in surface and ground water.

Table 6. Percent Recoveries of Carbaryl Detected by the NAWQA GC/MS Method in Laboratory Control Spikes and Field Matrix Spikes at a Spiking level of 0.1 µg/L

Sample Type	Number of	10^{th}	Median	Mean	90^{th}	Maximum
Field Matrix Spike	306	40	94.4	115.0	199.9	456
Laboratory Control	1000	20	93.0	99.6	185.1	329

The following disclaimer was taken verbatim from the provisional report by Martin (1999) and pertains to the data provided above on the recovery of carbaryl in the field matrix spike samples.

> *"The field matrix-spike data have not been reviewed thoroughly, are provisional, and are subject to change. Further review of the field-spike data is expected to identify spikes that have extremely high or low recoveries because the spikes either were improperly collected or incorrectly documented in the NAWQA QC data base. The expected result of further review is a data set of field matrix spikes with fewer extreme values than the provisional data set described in this paper; consequently, the provisional data set provides a conservative estimate of the quality of the NAWQA pesticide data. Interpretations of field matrix spike data in this paper are not expected to change greatly as a result of further review of the data, however, the statistics and confidence limits reported in the text and tables will change on further review (especially for pesticides with low numbers of field spikes [less than 50])."*

High-Performance Liquid Chromatography/Photodiode-Array Method

Another analytical method used in the NAWQA program for the analysis of carbaryl in water samples is the LC/PDA method described by Werner, *et al*., 1996. This method was used for the analysis of carbaryl in a limited number of samples as noted above. In this multi-residue method, the analytes are first removed from the water sample by sorption on a Carbopak-B solid phase extraction cartridge and are subsequently eluted from the solid phase, separated by HPLC and quantified by light absorption using a photodiode-array detector. The identity of each analyte is confirmed by the appropriate combination of retention time and light absorption characteristics. The recoveries for carbaryl spiked at different levels into three water samples and analyzed by this method is shown in Table 7 The recoveries ranged from 58% to 84% for the different water and spiking levels. Laboratory control spikes in organic-free water resulted in a mean recovery of 61% over a two-year sampling period. These results indicate reasonable levels of carbaryl recovery from each of the different types of water evaluated for the method.

Table 7. Recovery and Precision for Multiple Determinations of Carbaryl in LC/PDA Method for Carbaryl Spiked in Different Water Samples

Water type	Spike Concentration	Mean Recovery (%)	MDL Calculated
Organic-Free	0.1	82	0.008
Organic-Free	1.0	70	-
Surface[A]	0.1	84	0.016
Surface[A]	1.0	84	-
Ground[B]	0.1	58	0.018
Ground[B]	1.0	64	-
Organic-Free	0.5	61[C]	-

[A] Surface water was collected from the South Platte River at Englewood, Colorado.
[B] Ground water was collected from Jefferson County, Colorado (Arvada Well 14).
[C] National Water Quality Laboratory results produced using 5 operators and 7 instruments over 2 years (about 350 data points).

Summary of Surface Water Data from the California DPR Surface Water Database

In Section 5 pages 34 to 37 EPA has summarized surface water monitoring data from various sources. One source not included in this discussion is the California Surface Water Monitoring Database. The number of analyses and the detections of carbaryl residues reported in the database are summarized in Table 8. Carbaryl was detected at levels above the LOQ in only 5.1% of the 2,690 samples analyzed. The mean concentration of carbaryl in the 140 samples above the LOQ was 0.42 ppb. The highest concentration of carbaryl that was detected was 8.4 ppb.

An analysis of the data in the California Department of Pesticide Regulation's surface water database as of July 15, 2000 was conducted for carbaryl. The following summary of the contents of the database is adapted from information provided by the California DPR. The database contains monitoring results for pesticides in samples taken from California rivers, creeks, urban streams, agricultural drains, the Delta, and urban stormwater runoff. As of July 15, 2000, the database contained the results of 30 studies conducted by federal, state, and local agencies, private industry, and an environmental group. A total of 4,660 samples were taken in 16 counties from January 1991 through March 2000. Each record in the database is the result of one analysis for a pesticide active ingredient or breakdown product. The database contains a total of 92,296 analytical records. Only information on the analytical detection of carbaryl in these water samples is summarized in Table 8 below.

Table 8. Carbaryl Detections Reported in California DPR Surface Water Monitoring Database

Land Use	Number	**<=LOQ**		**>0.003 to**		**>0.01 to 0.1**		**>0.1 to 1 ppb**		**>1 ppb**	
		No.	%	No.	%	No.	%	No.	%	No.	%
All Samples	2690	2553	94.91	13	0.48	55	2.04	55	2.04	14	0.52

Concentrations of analytical results that are reported below the limit of quantification are reported as a zero in the database concentration field. The LOQs for the different methods used to generate the data contained in the database ranged from 0.003 to 0.5 µg/L, with a majority of the samples analyzed with an LOQ of 0.05 µg/L or less (Table 9) .

Table 9. Limits of Quantification for Carbaryl Analytical Methods Reported in California DPR Surface Water Monitoring Database

LOQ (µg/L)	0.003	0.041	0.044	0.05	0.07	0.1	0.5
Number of	267	238	168	1353	92	53	146

2. Ground Water Concentrations

In Section 5 page 34 EPA summarized information on the detection of carbaryl in groundwater from the EPA Pesticides in Groundwater Database, the EPA STORET database and the NAWQA database. Each of the databases shows a pattern of very low levels of carbaryl detection in few groundwater resources. These analyses confirm several statements made by the Agency that carbaryl has limited potential to impact groundwater resources. However, on page 2 of the Memorandum issued June 28, 2001, in conjunction with the EFED RED chapter for carbaryl, EPA is requiring additional information on "Surface and groundwater monitoring in urban and suburban use areas (non-guideline)." Based on the characteristics of carbaryl and the available data demonstrating limited impact of carbaryl on ground water resources, additional studies to evaluate the potential for carbaryl to contaminate groundwater are unnecessary and unwarranted.

Summary of Ground Water Data from the NAWQA Program

In Section 5, pages 33 - 34, EPA has summarized ground water monitoring data available for carbaryl. The database that contains the most extensive evaluation of the impact of the most recent uses of carbaryl on ground water is the NAWQA database. One deficiency of the NAWQA program is that samples are targeted to agricultural and urban areas but not to areas treated with the specific chemical being analyzed. However, given the use patterns of carbaryl, the use of carbaryl has certainly occurred near a number of these wells. Another deficiency is that when residues are found, that while they may be representative of residues in ground water, they may not be representative of residues in ground water used for drinking water due to the location of the sampled wells relative to potable drinking water wells.

EPA cited a 1998 review of the NAWQA database by Kolpin and stated:

> *"Carbaryl was detected at greater than the detection limit (0.003 µg/L) in 1.1 % of groundwater samples from 1034 sites across the U.S. by U.S.G.S. NAQWA (sic) program. The maximum observed concentration was 0.021 µg/L."*

This 1998 analysis has been extended by additional study data collected by the NAWQA program. The additional data continue to show a limited number of low level detections of carbaryl in ground water samples. Table 10 below summarizes a more recent provisional review by Kolpin (2001) of the updated NAWQA database. Not all of the water samples were used to calculate the summary statistics as noted by Kolpin:

> *"To preclude bias in these summary statistics from wells that were sampled more than once, the data set was condensed such that each well had a single pesticide analysis. This generally was the first sample collected. However, subsequent samples were selected if these samples contained more pesticide data (i.e., a larger number of pesticides were analyzed). Wells that were designed to be a part of both a land-use study and a major aquifer survey were used in each summary. Because of*

uncertainties in the source of water and contributing land-use area, springs and drains were excluded from these summaries."

Table 10. Carbaryl Detections Reported in Pesticides in Ground Water Update (Kolpin, 2001)

Site Type	**Number**	**Carbaryl Detection Frequency (%)**				**Maximum**
		All	**>=0.01**	**>=0.05**	**>=0.10**	
Agricultural Land-	1244	0.40	0.16	0.0	0.0	0.019
Urban Land-Use	634	2.1	1.3	0.0	0.0	0.031
Major Aquifers	1849	0.59	0.54	0.05	0.05	0.539

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Confidential Business Attachment

APPENDIX 1

Surface Water Monitoring for Residues of Carbaryl in High Use Areas of the United States (Stone Environmental, Inc. Report #99-1005-F) (hard copy provided).

Confidential Business Attachment

APPENDIX 2

Calculation of County Average Carbaryl Use Rates (hard copy provided)